

# **EXHIBIT 5**

Reynolds M. Delgado III, M.D.

Page 1

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968

SCOTTIE VEGA, Individually and as  
next friend of Christopher Vega,  
a minor and surviving natural  
child of Mimi Rivera-Vega,

MDL NO.  
2:09-CV-0768

Plaintiff,

v.

ACTAVIS TOTOWA, LLC, et al.,

Defendants.

ORAL DEPOSITION OF

REYNOLDS M. DELGADO III, M.D., F.A.C.C.

Monday, October 19, 2009

ORAL DEPOSITION OF REYNOLDS M.

DELGADO III, M.D., F.A.C.C., produced as a witness  
at the instance of the Actavis Defendants and duly  
sworn, was taken in the above-styled and numbered  
cause on the above-referenced date, from 10:32 a.m.  
to 4:08 p.m., before Michael E. Miller, RDR, CRR,  
CLR, Notary Public in and for the State of Texas,  
reported by realtime stenographic means at  
Williamson & Rusnak, 4310 Yoakum Boulevard, Houston,



Reynolds M. Delgado III, M.D.

Page 2

1 Texas, pursuant to the Federal Rules of Civil  
2 Procedure.

3 APPEARANCES

4 FOR PLAINTIFFS:

5 WILLIAMSON & RUSNAK  
4310 Yoakum Boulevard  
6 Houston, Texas 77006  
Phone: (713) 223-3330  
7 Fax: (713) 223-0001  
8 Jimmy Williamson, Esquire  
jwilliamson@jimmywilliamson.com

9  
10 Cyndi Moss Rusnak, Esquire  
crusnak@jimmywilliamson.com

11  
12 FOR ACTAVIS DEFENDANTS:

13 TUCKER, ELLIS & WEST, LLP  
925 Euclid Avenue  
14 Suite 1500  
Cleveland, Ohio 44115-1414  
15 Phone: (216) 592-5000  
Fax: (216) 592-5009  
16  
17 Matthew P. Moriarty, Esquire  
matthew.moriarty@tuckerellis.com

18  
19 FOR MYLAN DEFENDANTS:

20 SHOOK, HARDY & BACON, LLP  
JPMorgan Chase Tower  
21 600 Travis Street, Suite 1600  
Houston, Texas 77002-2911  
22 Phone: (713) 227-8008  
Fax: (713) 227-9508  
23  
24 Hunter K. Ahern, Esquire  
hahern@shb.com

25

Reynolds M. Delgado III, M.D.

Page 3

1	INDEX	
2	REYNOLDS M. DELGADO III, M.D., F.A.C.C.	
3	October 19, 2009	
4	APPEARANCES	2
5	PROCEEDINGS	6
6		
7	EXAMINATION OF	
8	REYNOLDS M. DELGADO III, M.D., F.A.C.C.:	
9	BY MR. MORIARTY	6
10	BY MS. AHERN	170
11	BY MR. MORIARTY	187
12		
13	CHANGES AND SIGNATURE	193
14	REPORTER'S CERTIFICATION	195
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

Reynolds M. Delgado III, M.D.

Page 4

1	DEPOSITION EXHIBITS		
2	REYNOLDS M. DELGADO III, M.D., F.A.C.C.		
3	October 19, 2009		
4	NUMBER	DESCRIPTION	MARKED
5	Exhibit 1	Medical Record (MVSLE[4]:1936)	69
6	Exhibit 2	Medical Record (MVSLE[4]:1232)	71
7	Exhibit 3	Medical Record (MVSLE[4]:1391)	71
8	Exhibit 4	Medical Record (MVSLE[4]:3353)	72
9	Exhibit 5	Medical Record (MVSLE[4]:3169)	72
10	Exhibit 6	Medical Record (MVSLE:1307)	73
11	Exhibit 7	Medical Record (MVSLE[4]:3515)	143
12	Exhibit 8	Medical Record (MVSLE[4]:3523)	143
13	Exhibit 9	Death Certificate	159
14	Exhibit 10	Curriculum Vitae of Reynolds M. Delgado, III, M.D., F.A.C.C. (MIMI_VEGA01551 - MIMI_VEGA01576)	7
15	Exhibit 11	10/14/09 Williamson Letter to Delgado, re: Mimi Rivera-Vega (MIMI_VEGA01545)	11
16	Exhibit 12	8/15/06 FDA Warning Letter to Actavis Totowa, LLC	13
17	Exhibit 13	2/1/07 FDA Revised Warning Letter to Actavis Totowa, LLC	14
18	Exhibit 14	4/25/08 Press Release, re: Digitek recall	14
19	Exhibit 15	1/9/09 FDA News Release, re: Permanent Injunction Against Actavis Totowa, LLC	15
20			
21			
22			
23			
24			
25			

Reynolds M. Delgado III, M.D.

Page 5

1

## DEPOSITION EXHIBITS

2

3

NUMBER

DESCRIPTION

MARKED

4

Exhibit 16

Urgent Drug Recall Notice

15

5

Exhibit 17

"Relationship of Serum Digoxin  
Concentration to Mortality and  
Morbidity in Women in the  
Digitalis Investigation Group  
Trial," by Adams, et al.

16

6

7

8

Exhibit 18

7/8/09 Article, "Facts and  
Myths about Generic Drugs"

81

9

Exhibit 19

PDR Entry for Lanoxin

162

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Reynolds M. Delgado III, M.D.

Page 6

1 PROCEEDINGS

2 (October 19, 2009 at 10:32 a.m.)

3 REYNOLDS M. DELGADO III, M.D., F.A.C.C.,

10:32:12 4 having been duly sworn, testified as follows:

10:32:12 5 EXAMINATION

10:32:12 6 BY MR. MORIARTY:

10:32:13 7 Q. Dr. Delgado, my name is Matthew

10:32:15 8 Moriarty. I represent the Actavis Defendants. They

10:32:19 9 manufacture Digitek.

10:32:20 10 Have you had your deposition taken

10:32:21 11 before in your career?

10:32:23 12 A. Yes.

10:32:23 13 Q. How many times?

10:32:24 14 A. Approximately seven.

10:32:27 15 Q. How many of those were medical

10:32:29 16 malpractice cases?

10:32:31 17 A. Approximately six.

10:32:34 18 Q. And what was the nonmedical malpractice

10:32:36 19 case?

10:32:37 20 A. During divorce proceedings.

10:32:41 21 Q. Okay. For a patient or for yourself?

10:32:44 22 A. Myself.

10:32:45 23 Q. All right. Of the medical malpractice

10:32:48 24 depositions, in how many of those were you the

10:32:52 25 treating physician as opposed to an independent,

Reynolds M. Delgado III, M.D.

Page 7

10:32:56 1 hired, expert witness?

10:32:57 2 A. Approximately 50/50; half.

10:33:04 3 Q. From those experiences, you know that

10:33:06 4 I'm going to ask you a number of questions out loud

10:33:09 5 and in plain English, and that you're required to

10:33:11 6 answer me out loud and in plain English, so that the

10:33:15 7 court reporter can take it down, correct?

10:33:17 8 A. Correct.

10:33:17 9 Q. If you don't understand my question,

10:33:19 10 please tell me, and I'll try to make it clear to

10:33:22 11 you, okay?

10:33:22 12 A. Yes.

10:33:23 13 Q. And I see you've brought a folder of

10:33:28 14 materials. If you need to refer to that folder of

10:33:32 15 materials for any details about Mimi Rivera-Vega,

10:33:38 16 you're welcome to do that, okay?

10:33:39 17 A. Yes.

10:33:46 18 (Delgado Deposition Exhibit 10

10:33:48 19 marked.)

10:33:48 20 BY MR. MORIARTY:

10:33:48 21 Q. Before you came in the room, I was

10:33:49 22 handed this CV, which I've had marked as Dr. Delgado

10:33:57 23 Exhibit 10. Do you see that?

10:33:58 24 A. Yes.

10:33:58 25 Q. Is that your CV?



Reynolds M. Delgado III, M.D.

Page 8

10:34:00 1 A. Yes.

10:34:00 2 Q. Is it up to date?

10:34:02 3 A. Yes.

10:34:02 4 Q. You can keep that there, if you want, by  
10:34:07 5 your right side.

10:34:09 6 Now, let's get back to these  
10:34:23 7 previous deposition experiences. Of the times that  
10:34:26 8 you were the independently hired expert, how many of  
10:34:33 9 those were for the plaintiff and how many for the  
10:34:36 10 medical providers?

10:34:38 11 A. Approximately two for the plaintiff, one  
10:34:42 12 for the defendant, I guess.

10:34:46 13 Q. Okay. The medical provider, hospital or  
10:34:49 14 a doctor?

10:34:52 15 A. It was a company, in this case.

10:34:54 16 Q. All right.

10:34:55 17 A. A corporation.

10:34:55 18 Q. And then did -- in the ones in which you  
10:34:58 19 were treating physician, were you -- did you end up  
10:35:02 20 being an expert for either the plaintiffs or the  
10:35:05 21 defendant medical providers?

10:35:07 22 A. Treating physician -- when I was a  
10:35:18 23 treating physician, there was one in which I was  
10:35:25 24 defendant [sic] for the plaintiff, and the others  
10:35:27 25 were for the -- as an expert witness on the defense,

Reynolds M. Delgado III, M.D.

Page 9

10:35:34 1 for the defense team.

10:35:36 2 Q. Have you ever been sued yourself for  
10:35:38 3 malpractice?

10:35:38 4 A. Yes.

10:35:38 5 Q. Were you deposed in that case?

10:35:40 6 A. Yes.

10:35:40 7 Q. Did it involve cardiac glycosides in any  
10:35:47 8 way?

10:35:47 9 A. No.

10:35:47 10 Q. Did it involve left ventricular assist  
10:35:53 11 device, or devices?

10:35:54 12 A. Yes.

10:35:54 13 Q. All right. When you're at your hospital  
10:35:58 14 talking to your colleagues, do you call them LVADs?

10:36:02 15 A. Yes.

10:36:02 16 Q. Can I do that today, because it's  
10:36:04 17 shorter?

10:36:04 18 A. Yes.

10:36:05 19 Q. All right. On how many cases have you  
10:36:13 20 been retained as an expert by Jimmy Williamson or  
10:36:17 21 any member of his law firm?

10:36:19 22 A. Twice.

10:36:19 23 Q. And were they both medical negligence  
10:36:23 24 cases?

10:36:28 25 A. Yes, as I understand the word.

Reynolds M. Delgado III, M.D.

Page 10

10:36:31 1 Q. Like a malpractice case, as opposed to a  
10:36:36 2 pharmaceutical products liability case.

10:36:38 3 A. Oh. One was one; one was the other.

10:36:41 4 Q. Okay. What was the pharmaceutical  
10:36:43 5 products liability case? What was the product  
10:36:46 6 involved?

10:36:46 7 A. It was a contrast agent used to image  
10:36:56 8 patients with magnetic resonance imaging.

10:37:01 9 Q. Is it a gadolinium case?

10:37:04 10 A. Yes.

10:37:05 11 Q. Did that patient have the -- I forget  
10:37:08 12 what that disease is they claim is the signature  
10:37:11 13 disease, because I've been away from gadolinium for  
10:37:14 14 a few months; but did the patient have that disease?

10:37:18 15 A. I believe so, yes.

10:37:19 16 Q. All right. And then what was the other  
10:37:22 17 type of case in which he retained you as an expert?

10:37:25 18 A. A patient who had been treated at an  
10:37:29 19 institution and given a fatal diagnosis, which  
10:37:36 20 she -- which was a misdiagnosis, which she did not  
10:37:41 21 have. And she received treatment for that, and that  
10:37:43 22 ended up harming her.

10:37:44 23 Q. Was that an amyloidosis case?

10:37:46 24 A. Yes.

10:37:47 25 Q. And for how many years have you known

Reynolds M. Delgado III, M.D.

Page 11

10:37:50 1 Mr. Williamson?

10:37:52 2 A. Perhaps, three.

10:37:53 3 Q. Okay. Other than the two cases on which  
10:37:56 4 he hired you as an expert, do you have any other  
10:37:59 5 professional relationship with him?

10:38:00 6 A. No.

10:38:00 7 Q. Do you have any social relationship with  
10:38:02 8 him?

10:38:02 9 A. No.

10:38:02 10 Q. Never been to his house, things of that  
10:38:06 11 nature?

10:38:06 12 A. Correct.

10:38:06 13 (Delgado Deposition Exhibit 11  
10:38:06 14 marked.)

10:38:06 15 BY MR. MORIARTY:

10:38:06 16 Q. Okay. Let's talk about what you've  
10:38:21 17 reviewed. You've known for a little bit that we  
10:38:24 18 were going to take your deposition today.

10:38:32 19 Mr. Williamson handed me this letter that I've had  
10:38:35 20 marked as Dr. Delgado Exhibit 11. Do you see that?

10:38:40 21 A. Yes.

10:38:41 22 Q. And this was from his office to you,  
10:38:43 23 correct?

10:38:43 24 A. Yes.

10:38:43 25 Q. So have you reviewed these six items on

Reynolds M. Delgado III, M.D.

Page 12

10:38:46 1 this list?

10:38:47 2 A. Yes.

10:38:47 3 Q. Do you have the warning letter that is  
10:38:51 4 item 2 and the revised warning letter that is item 3  
10:38:56 5 and the recall documents that are 4, 5 and 6 with  
10:39:02 6 you today?

10:39:03 7 A. I should, yes.

10:39:04 8 Q. Okay. Could you pull those out for me?  
10:39:11 9 I don't need the Walmart records. I just need the  
10:39:15 10 other things.

10:39:15 11 A. So that would be this, this and this,  
10:39:25 12 this and this.

10:39:32 13 MR. MORIARTY: Can I just mark  
10:39:33 14 these, or do I need to have copies made?

10:39:35 15 MR. WILLIAMSON: I'll do whatever  
10:39:36 16 you want. You can -- on those documents, you can  
10:39:41 17 just mark them.

10:39:42 18 MR. MORIARTY: Okay.

10:39:43 19 MR. WILLIAMSON: But his original  
10:39:44 20 chart, he wants to keep today. To the extent you  
10:39:47 21 mark it, I'll figure out a mutually agreeable way to  
10:39:50 22 do the copying.

10:39:51 23 MR. MORIARTY: Yeah. That's fine.

10:39:54 24 MR. WILLIAMSON: Subject to  
10:39:55 25 Dr. Delgado's -- I mean, he wants to keep his chart,

Reynolds M. Delgado III, M.D.

Page 13

10:39:57 1 and so we'll figure out a way that is acceptable to  
10:40:03 2 him and us.

10:40:04 3 MR. MORIARTY: Okay.

10:40:05 4 Mark that, please.

10:40:06 5 (Delgado Deposition Exhibit 12  
10:40:14 6 marked.)

10:40:14 7 BY MR. MORIARTY:

10:40:14 8 Q. I've marked Dr. Delgado Exhibit 12.

10:40:16 9 This is an August 15th, 2006, FDA warning letter.

10:40:21 10 Do you see that?

10:40:21 11 A. Yes.

10:40:22 12 Q. And it corresponds with item 2 on this  
10:40:26 13 Exhibit 11 list, correct?

10:40:27 14 A. Correct.

10:40:30 15 Q. Do you know if this has anything to do  
10:40:32 16 with Digitek?

10:40:39 17 A. In general, yes.

10:40:40 18 Q. In general, you know?

10:40:41 19 A. Yes.

10:40:42 20 Q. Does it have anything to do with  
10:40:44 21 Digitek?

10:40:44 22 A. Yes.

10:40:45 23 Q. All right. This is the --

10:40:50 24 MR. WILLIAMSON: Is that a trick

10:40:51 25 question? Can I see that document you just marked?

Reynolds M. Delgado III, M.D.

Page 14

10:40:54 1 MR. MORIARTY: Right there.

10:40:58 2 MR. WILLIAMSON: The one you were

10:40:59 3 referring to.

10:41:02 4 (Delgado Deposition Exhibit 13

10:41:08 5 marked.)

10:41:08 6 BY MR. MORIARTY:

10:41:08 7 Q. And Delgado Exhibit 13 is the

10:41:12 8 February 1st, 2000, revised warning letter, correct?

10:41:15 9 A. Yes.

10:41:15 10 Q. Corresponds with item 3 on the

10:41:18 11 Delgado 11 list; is that correct?

10:41:19 12 A. Yes. Yes.

10:41:36 13 Q. All right. Now, I'm holding in my hands

10:41:38 14 here these two recall documents. Do you know which

10:41:44 15 corresponds to item 4 and which corresponds to

10:41:47 16 item 5? I think the one to the right is number 5.

10:41:53 17 A. This would be 4, yes.

10:41:53 18 (Delgado Deposition Exhibit 14

10:41:53 19 marked.)

10:41:56 20 BY MR. MORIARTY:

10:41:56 21 Q. Okay. So Dr. Delgado Exhibit 14

10:42:05 22 corresponds to number 4 on the list in Delgado

10:42:13 23 Exhibit 11, correct?

10:42:14 24 A. Yes.

10:42:14 25 Q. And then Exhibit 15 corresponds with

Reynolds M. Delgado III, M.D.

Page 15

10:42:18 1 Exhibit 5?

10:42:24 2 (Delgado Deposition Exhibit 15

10:42:25 3 marked.)

10:42:25 4 BY MR. MORIARTY:

10:42:26 5 Q. Correct?

10:42:26 6 A. Yes.

10:42:37 7 Q. And then -- I think I made a mistake

10:42:45 8 here. Okay. I made a mistake. Exhibit 15 is

10:43:01 9 actually this FDA news release dated 1/9/2009,

10:43:06 10 correct?

10:43:07 11 A. January, yes.

10:43:07 12 (Delgado Deposition Exhibit 16

10:43:07 13 marked.)

10:43:08 14 BY MR. MORIARTY:

10:43:08 15 Q. Okay. So I made a mistake.

10:43:10 16 And then Exhibit 16 is going to be

10:43:15 17 the urgent drug recall, which is number 5 on the

10:43:30 18 Dr. Delgado Exhibit 11 list, correct?

10:43:32 19 A. Yes.

10:43:32 20 Q. All right. I'll leave these here.

10:43:42 21 Now, in the notice of deposition I

10:43:44 22 had asked you to bring a research file, if you had

10:43:46 23 one, regarding digoxin. Did you bring any medical

10:43:51 24 research that you maintain regarding digoxin?

10:43:54 25 A. Yes.



Reynolds M. Delgado III, M.D.

Page 16

10:43:54 1 Q. And how many articles are there?

10:43:56 2 A. A single article.

10:43:59 3 Q. Some doctors have large files full of

10:44:03 4 paper. Do you keep research files like that?

10:44:08 5 A. No.

10:44:08 6 Q. All right. May I mark this?

10:44:14 7 A. Yes.

10:44:14 8 (Delgado Deposition Exhibit 17

10:44:14 9 marked.)

10:44:16 10 BY MR. MORIARTY:

10:44:16 11 Q. So Exhibit 17 is the one article you

10:44:19 12 have, and this is a -- is this a follow-up to the

10:44:26 13 DIG trial?

10:44:27 14 A. Yes.

10:44:28 15 Q. All right. And it's an article by

10:44:30 16 Kirkwood Adams, et cetera, right?

10:44:33 17 A. Yes.

10:44:34 18 Q. Has Mr. Williamson or anyone in his

10:44:47 19 office sent you any other material besides what we

10:44:50 20 may have already marked as an exhibit?

10:44:54 21 A. Yes.

10:44:57 22 Q. What else did he send you?

10:44:59 23 A. Boxes of the bulk hospital medical

10:45:05 24 records, St. Luke's Hospital.

10:45:08 25 Q. Okay. Anything else?

Reynolds M. Delgado III, M.D.

Page 17

10:45:09 1 A. No.

10:45:09 2 Q. The article which I believe I marked  
10:45:11 3 Exhibit 17, is that something you found and had, or  
10:45:14 4 is it something that Mr. Williamson sent you?

10:45:17 5 A. I found this one.

10:45:18 6 Q. Did you meet with Mr. Williamson this  
10:45:24 7 morning to prepare for today's deposition?

10:45:27 8 A. Just prior to coming into the room.

10:45:32 9 Q. For how long did you meet?

10:45:33 10 A. 15 minutes.

10:45:35 11 Q. And on how many occasions before today  
10:45:38 12 have you met with him in person to discuss this  
10:45:41 13 case?

10:45:41 14 A. One.

10:45:42 15 Q. On how many occasions before today have  
10:45:45 16 you spoken with him or a member of his staff over  
10:45:48 17 the telephone?

10:45:49 18 A. Regarding this case?

10:45:56 19 Q. Yes. I'm sorry.

10:45:58 20 A. Perhaps, one.

10:46:02 21 Q. Other than your own staff, to arrange  
10:46:06 22 for the logistics of being here today and  
10:46:09 23 accommodating this on a business day, have you  
10:46:14 24 talked to anybody else about Mimi Rivera's Digitek  
10:46:21 25 litigation lawsuit?

Reynolds M. Delgado III, M.D.

Page 18

10:46:21 1 A. No.

10:46:21 2 Q. I'm sure this is in your CV, but are you  
10:46:31 3 licensed to practice medicine in Texas?

10:46:33 4 A. Yes.

10:46:33 5 Q. Any other states?

10:46:35 6 A. No.

10:46:35 7 Q. Are you required to take continuing  
10:46:44 8 medical education?

10:46:45 9 A. Yes.

10:46:46 10 Q. Are you up to date, consistently, with  
10:46:48 11 your requirements in that regard?

10:46:50 12 A. Yes.

10:46:51 13 Q. Do you ever attend conferences, or have  
10:46:54 14 you attended conferences in the last few years which  
10:46:57 15 included topics regarding cardiac glycosides?

10:47:02 16 A. Yes.

10:47:02 17 Q. Tell me generally what those conferences  
10:47:06 18 would have been.

10:47:08 19 A. I frequently go to conferences that  
10:47:11 20 involve heart failure in general, and that's the  
10:47:14 21 primary disease entity that the cardiac glycosides  
10:47:19 22 are used to treat. Heart Society of America would  
10:47:23 23 be a good example. International Society of  
10:47:28 24 Heart/Lung Transplant would be another good example.

10:47:32 25 Q. And they're talking about the use of

Reynolds M. Delgado III, M.D.

Page 19

10:47:35 1 cardiac glycosides, different strategies and  
10:47:38 2 therapies in the modern era or its use in various  
10:47:42 3 forms of heart failure; is that correct?

10:47:44 4 A. These are actually meetings, large  
10:47:48 5 meetings, with literally hundreds of talks; and at  
10:47:53 6 some of those talks, the use of cardiac glycosides  
10:47:57 7 is discussed.

10:47:57 8 Q. All right. Have you ever published any  
10:48:01 9 articles specifically about the use of digoxin?

10:48:08 10 A. No.

10:48:09 11 Q. And I know that some cardiologists are  
10:48:17 12 subspecialists. Are you generally a heart-failure  
10:48:20 13 cardiologist?

10:48:21 14 A. Yes.

10:48:21 15 Q. Do you have any special training in  
10:48:30 16 epidemiology?

10:48:31 17 A. No.

10:48:31 18 Q. Do you have any special training in  
10:48:33 19 pharmacology?

10:48:33 20 A. No.

10:48:33 21 Q. Do you consider yourself to be an expert  
10:48:36 22 in pharmacology?

10:48:38 23 A. No, I wouldn't say so.

10:48:48 24 Q. Do you have any special training in  
10:48:50 25 pharmacokinetics or toxicology?

Reynolds M. Delgado III, M.D.

Page 20

10:48:52 1 A. Nothing special, no.

10:48:54 2 Q. You know, obviously as you marched  
10:48:57 3 through medical school and your residency and your  
10:49:00 4 practice, these are issues that you have to deal  
10:49:02 5 with, correct?

10:49:03 6 A. Yes.

10:49:03 7 Q. And so when I ask, have you had any  
10:49:06 8 special training, I mean outside the routine medical  
10:49:10 9 school setting.

10:49:11 10 A. Correct.

10:49:11 11 Q. So do you consider yourself to be an  
10:49:14 12 expert in either pharmacokinetics or toxicology?

10:49:20 13 A. Depends on how you define that.

10:49:25 14 Q. Define which?

10:49:26 15 A. "Expert."

10:49:28 16 Q. Well, how do you define it?

10:49:30 17 MR. WILLIAMSON: He doesn't define  
10:49:31 18 it; the Court does.

10:49:32 19 BY MR. MORIARTY:

10:49:34 20 Q. How do you define it as a doctor?

10:49:37 21 A. Depends on the premise of the question  
10:49:48 22 that's being asked.

10:49:49 23 Q. Sure. Let me ask it a different way,  
10:49:52 24 then.

10:49:52 25 Have you ever published any articles

Reynolds M. Delgado III, M.D.

Page 21

10:49:54 1 regarding pharmacokinetics or toxicology?

10:49:58 2 A. I've published articles in which those  
10:50:02 3 topics are part of the article, but not specifically  
10:50:06 4 about those topics.

10:50:08 5 Q. Have you ever done an evidentiary search  
10:50:10 6 regarding toxicology or pharmacokinetics?

10:50:16 7 A. Only as part of my routine medical  
10:50:19 8 school training, residency training.

10:50:21 9 Q. Do you have any military service?

10:50:26 10 A. Excuse me?

10:50:27 11 Q. Any military service?

10:50:30 12 A. No.

10:50:30 13 Q. Do you have -- currently have teaching  
10:50:34 14 appointments?

10:50:35 15 A. Yes.

10:50:35 16 Q. Where?

10:50:35 17 A. University of Texas Health Science  
10:50:38 18 Center in Houston and Baylor College of Medicine.

10:50:41 19 Q. Are you teaching in a classroom or only  
10:50:46 20 in the hospital setting with residents and fellows?

10:50:50 21 A. It's a little of both. Mostly hospital  
10:50:54 22 rounding.

10:50:56 23 Q. To the best of your memory, were either  
10:51:01 24 you or any of your colleagues at Texas Heart  
10:51:07 25 Institute involved in the PROVED, RADIANCE or DIG

Reynolds M. Delgado III, M.D.

Page 22

10:51:14 1 trials?

10:51:14 2 A. No.

10:51:25 3 Q. Are you aware that in 2009, the ACCF and  
10:51:31 4 the AHA came out with new guidelines regarding the  
10:51:33 5 management of heart failure?

10:51:34 6 A. Yes.

10:51:35 7 Q. Were you or any of your colleagues at  
10:51:38 8 Texas Heart involved in the rewrite or update of  
10:51:41 9 those guidelines?

10:51:43 10 A. No.

10:51:43 11 Q. Have you read those guidelines?

10:51:47 12 A. Not in total.

10:51:49 13 Q. Do you routinely subscribe to or review  
10:51:56 14 medical journals?

10:51:57 15 A. Yes.

10:51:57 16 Q. Which ones?

10:51:58 17 A. The Journal of the American College of  
10:52:02 18 Cardiology, the New England Journal of Medicine,  
10:52:07 19 Journal of the American Medical Association, journal  
10:52:11 20 of the International Society of Heart/Lung  
10:52:14 21 Transplant.

10:52:14 22 Q. Are there any other journals or freebies  
10:52:18 23 that you get specifically relating to heart-failure  
10:52:22 24 topics?

10:52:24 25 A. Occasionally. Congestive heart failure,

Reynolds M. Delgado III, M.D.

Page 23

10:52:28 1 for example.

10:52:28 2 Q. Is that a hard journal or an online  
10:52:32 3 journal?

10:52:33 4 A. It's a hard copy.

10:52:38 5 Q. And are there any particular online  
10:52:40 6 databases that you consult with on a regular basis?

10:52:42 7 A. MEDLINE, National Library of Medicine.

10:52:52 8 Q. As far as textbooks, do you keep any  
10:52:55 9 cardiology textbooks in your home or office medical  
10:52:59 10 library?

10:52:59 11 A. Office, yes.

10:53:01 12 Q. Do you have Braunwald's text?

10:53:04 13 A. Yes.

10:53:05 14 Q. Do you have Hurst's text?

10:53:06 15 A. No.

10:53:07 16 Q. Do you have Don Mann's heart-failure  
10:53:11 17 text?

10:53:13 18 A. That's Doug Mann.

10:53:14 19 Q. I'm sorry. What did I say?

10:53:15 20 A. Don. You said Don.

10:53:17 21 Q. I'm sorry.

10:53:18 22 A. It's Doug.

10:53:19 23 Q. Doug. I'm sorry.

10:53:20 24 A. I'm a contributing author to that text.

10:53:22 25 Q. Which chapter did you write in his text?



Reynolds M. Delgado III, M.D.

Page 24

10:53:25 1 A. The one related to left ventricular  
10:53:29 2 assist devices.

10:53:30 3 Q. Did he -- did Doug Mann, sorry, used to  
10:53:33 4 be at Texas Heart?

10:53:33 5 A. Yes.

10:53:34 6 Q. And as far as these textbooks, either  
10:53:44 7 Dr. Mann's or Braunwald's, do you refer to them from  
10:53:48 8 time to time?

10:53:50 9 A. Occasionally.

10:53:51 10 Q. Do you keep the PDR in your home or  
10:54:02 11 office medical library?

10:54:03 12 A. In the office, yes.

10:54:05 13 Q. Do you consult with it from time to  
10:54:07 14 time?

10:54:07 15 A. Occasionally.

10:54:08 16 Q. What other sources do you use, either  
10:54:12 17 hard-copy or online, to learn about pharmaceutical  
10:54:14 18 products that are on the market?

10:54:16 19 A. There is a program that is used in the  
10:54:21 20 hospital frequently, ePrescribe; and then as part of  
10:54:25 21 our electronic medical records in the office, there  
10:54:28 22 is a pharmacology database.

10:54:33 23 Q. And is ePrescribe a Texas Heart program,  
10:54:43 24 or is it a commercially available program?

10:54:45 25 A. I'm not sure where it's available. I

Reynolds M. Delgado III, M.D.

Page 25

10:54:48 1 just know that it's something that's accessible on  
10:54:52 2 the St. Luke's portal, hospital portal.

10:54:56 3 Q. All right. And then what about the one  
10:54:58 4 you said you have in your office?

10:54:59 5 A. That is an EMR, or electronic medical  
10:55:03 6 record, and it is a web-based program that is used  
10:55:09 7 to generate our medical records; and it has a  
10:55:18 8 pharmacology prescribing database incorporated into  
10:55:22 9 it.

10:55:25 10 Q. And I assume that's a commercially  
10:55:27 11 available product that your office bought?

10:55:30 12 A. Yes.

10:55:30 13 Q. When I refer to "your office," how many  
10:55:33 14 offices do you actually have?

10:55:35 15 A. Two.

10:55:35 16 Q. And, for example, do you have an office  
10:55:39 17 at St. Luke's Hospital?

10:55:41 18 A. Yes.

10:55:41 19 Q. And then what's your other office?

10:55:45 20 A. It's at the O'Quinn Medical Towers,  
10:55:49 21 which is across the street from St. Luke's Hospital.

10:55:52 22 Q. What is the facility called that's in  
10:55:55 23 the Oak Twin Towers?

10:55:57 24 A. It is a private practice.

10:55:58 25 Q. What's it called?

Reynolds M. Delgado III, M.D.

Page 26

10:55:59 1 A. Delgado Cardiovascular Associates.

10:56:04 2 Q. All right. And what is Texas Heart?

10:56:05 3 A. Texas Heart is a not-for-profit teaching

10:56:11 4 and research organization that is responsible for

10:56:17 5 the teaching/research liaison to the hospital and

10:56:20 6 the medical schools.

10:56:22 7 Q. And what is your affiliation with Texas

10:56:26 8 Heart? What do you call it?

10:56:27 9 A. Medical staff member. There's no real

10:56:34 10 rank other than president, I guess; but all the rest

10:56:37 11 of us who are members of Texas Heart are members.

10:56:41 12 Q. All right. So you have a private office

10:56:43 13 where you see patients, and then you have privileges

10:56:46 14 at St. Luke's?

10:56:46 15 A. Correct.

10:56:47 16 Q. And then you have this appointment at

10:56:49 17 Texas Heart, correct?

10:56:50 18 A. Correct.

10:56:50 19 Q. And is St. Luke's your primary hospital?

10:56:54 20 A. Yes.

10:56:54 21 Q. When was the last time you read a

10:57:03 22 digoxin product package insert?

10:57:09 23 A. I can't remember if I ever did such a

10:57:13 24 thing.

10:57:13 25 Q. All right. Have you ever been a

Reynolds M. Delgado III, M.D.

Page 27

10:57:19 1 consultant to a pharmaceutical company?

10:57:21 2 A. No. No.

10:57:28 3 Q. And have you ever worked for one as an  
10:57:31 4 employee?

10:57:32 5 A. No.

10:57:32 6 Q. Have you ever written to a  
10:57:37 7 pharmaceutical company about -- to get more  
10:57:41 8 information about any of the drugs that you  
10:57:43 9 prescribe?

10:57:43 10 A. Not that I can remember.

10:57:50 11 Q. All right. Now, let me go off in  
10:57:59 12 another direction for a minute. I want to talk  
10:58:02 13 about medical records in general, okay?

10:58:05 14 The file that you brought, is that  
10:58:09 15 your office record regarding Mimi Rivera-Vega?

10:58:16 16 A. Yes.

10:58:17 17 Q. And in medical school and through your  
10:58:19 18 residency, I assume you were taught in general how  
10:58:22 19 to keep medical records, correct?

10:58:24 20 A. Yes.

10:58:24 21 Q. And whether it's the joint commission on  
10:58:32 22 the accreditation of hospitals or the hospital like  
10:58:35 23 St. Luke's itself, I assume that there are protocols  
10:58:39 24 and processes that you follow to keep hospital  
10:58:41 25 charts, right?

Reynolds M. Delgado III, M.D.

Page 28

10:58:42 1 A. Correct.

10:58:42 2 Q. And in general, when you are charting on  
10:58:47 3 a patient, whether it's in your office or in a  
10:58:49 4 hospital, for the most part, to the extent you can,  
10:58:53 5 those are supposed to be contemporaneous entries,  
10:58:57 6 along with the care that is being provided?

10:59:00 7 A. Yes.

10:59:01 8 Q. All right. Would it be fair for me to  
10:59:06 9 say that some of the purposes for medical records  
10:59:10 10 are charting a baseline for a patient against which  
10:59:17 11 you can compare development or deterioration?

10:59:21 12 A. Yes.

10:59:21 13 Q. And sort of a guide to tell you what is  
10:59:28 14 either working for or not working for a particular  
10:59:31 15 patient?

10:59:31 16 A. Yes.

10:59:32 17 Q. And are they also -- medical records  
10:59:35 18 also a communication tool?

10:59:40 19 A. Yes.

10:59:41 20 Q. So that you can communicate with your  
10:59:44 21 nurses or your physicians assistants, whatever you  
10:59:47 22 use in the office; is that right?

10:59:48 23 A. Yes.

10:59:48 24 Q. And then in a hospital setting, you're  
10:59:51 25 communicating with -- you're either communicating

Reynolds M. Delgado III, M.D.

Page 29

10:59:53 1 with or being communicated to consultants, nurses,  
10:59:58 2 laboratories, radiology departments, things of that  
11:00:01 3 nature, right?

11:00:02 4 A. Yes.

11:00:03 5 Q. All right. And I assume that when  
11:00:06 6 you're teaching, you teach your students all of  
11:00:09 7 these principles regarding medical records; is that  
11:00:13 8 right?

11:00:14 9 A. Yes.

11:00:14 10 Q. And if you're going to change a medical  
11:00:16 11 record for whatever reason, is there a specific  
11:00:18 12 process that you go through to do that?

11:00:20 13 A. Yes.

11:00:21 14 Q. Do most prescription medicines have  
11:00:34 15 risks associated with them?

11:00:35 16 A. Yes.

11:00:39 17 Q. And sometimes with certain drugs, those  
11:00:45 18 risks can include death; is that right?

11:00:49 19 A. Yes.

11:00:49 20 Q. And when you make a decision to  
11:00:53 21 prescribe a drug for a particular patient, do you  
11:00:57 22 make a risk-benefit analysis?

11:01:00 23 A. Yes.

11:01:00 24 Q. In other words, you ultimately conclude,  
11:01:03 25 if you prescribe it, that the benefit is going to

Reynolds M. Delgado III, M.D.

Page 30

11:01:06 1 outweigh the risk, right?

11:01:08 2 A. Correct.

11:01:08 3 Q. Let me ask you some questions about your  
11:01:24 4 practice in these years from, say, 2000 to 2008; and  
11:01:31 5 I know that spans a long time.

11:01:32 6 Did you have Delgado Cardiovascular  
11:01:41 7 private practice back in 2002?

11:01:47 8 A. Yes.

11:01:47 9 Q. How many other cardiologists were in  
11:01:49 10 that practice in the years 2002 to 2008?

11:01:56 11 A. It's changed. It's fluctuated. So at  
11:02:01 12 the greatest, there were three of them, myself; and  
11:02:12 13 currently, there's only myself and I office-share  
11:02:18 14 with another doctor and have affiliation with five  
11:02:20 15 others.

11:02:21 16 Q. Five others who are not technically part  
11:02:23 17 of your practice, right?

11:02:25 18 A. Correct.

11:02:25 19 Q. And when you say "affiliate with,"  
11:02:28 20 you're talking about cross-coverage, things of that  
11:02:31 21 nature, right?

11:02:31 22 A. Yes.

11:02:32 23 Q. All right. And then how many  
11:02:35 24 cardiologists are part of Texas Heart?

11:02:37 25 A. There's around 40, roughly.

Reynolds M. Delgado III, M.D.

Page 31

11:02:42 1 Q. How many of them are heart-failure  
11:02:46 2 cardiologists?

11:02:47 3 A. Five.

11:02:49 4 Q. In your private office practice, do you  
11:02:54 5 employ Registered Nurses, physicians assistants,  
11:02:59 6 anything like that?

11:03:01 7 A. No.

11:03:02 8 Q. At your private office, do you give any  
11:03:19 9 handouts regarding cardiac glycosides?

11:03:22 10 A. No.

11:03:22 11 Q. Do you know whether they give any  
11:03:23 12 handouts out at St. Luke's Hospital about cardiac  
11:03:28 13 glycosides?

11:03:28 14 A. No.

11:03:28 15 Q. No, you don't know, or no, they don't  
11:03:30 16 give them?

11:03:31 17 A. They don't give them.

11:03:32 18 Q. All right. In general, if you are  
11:03:45 19 looking at a patient, what lab results do you focus  
11:03:48 20 on when assessing their renal function?

11:03:51 21 A. BUN, creatinine, sodium.

11:04:01 22 Q. What about GFR or EGFR?

11:04:06 23 A. No, I don't use EGFR.

11:04:10 24 Q. Why not?

11:04:11 25 A. It's an estimate. It's often



Reynolds M. Delgado III, M.D.

Page 32

11:04:13 1 inaccurate.

11:04:14 2 Q. Okay. In February 2008, I believe one  
11:04:31 3 of your consultants characterized Mimi Rivera-Vega  
11:04:38 4 as being an end-stage heart-failure patient. Do you  
11:04:42 5 remember seeing that in any of your consultants'  
11:04:51 6 notes?

11:04:51 7 A. No.

11:04:51 8 Q. How would you have characterized Mimi  
11:04:54 9 Rivera-Vega as a heart-failure patient in, say,  
11:04:57 10 February of 2008, prior to the placement of her  
11:04:59 11 first LVAD?

11:05:00 12 A. She had severe heart failure and  
11:05:07 13 evolving shock.

11:05:10 14 Q. In patients who have heart failure in  
11:05:13 15 general, do some of them require multiple  
11:05:18 16 medications?

11:05:20 17 A. Yes.

11:05:20 18 Q. What I sometimes call poly-pharmacy.  
11:05:27 19 Have you ever heard that term?

11:05:28 20 A. Yes.

11:05:30 21 Q. And in patients who are taking a number  
11:05:32 22 of different medications, are they at increased risk  
11:05:36 23 for adverse drug events?

11:05:38 24 A. Yes.

11:05:44 25 Q. And can adverse drug events occur even

Reynolds M. Delgado III, M.D.

Page 33

11:05:56 1 if patients are taking appropriately labeled

11:06:00 2 pharmaceutical products in appropriate doses?

11:06:05 3 A. Yes.

11:06:08 4 Q. If a patient has underlying renal

11:06:14 5 insufficiency, does it increase the risk of adverse

11:06:17 6 reaction to a drug that is primarily cleared by the

11:06:21 7 kidney?

11:06:22 8 A. Yes.

11:06:23 9 Q. Is digoxin primarily cleared by the

11:06:26 10 kidney?

11:06:27 11 A. Yes.

11:06:28 12 Q. Now, you're a relatively young man, so I

11:06:37 13 assume that throughout the course of your medical

11:06:40 14 training, cardiac glycosides were part of what you

11:06:44 15 learned about; is that true?

11:06:45 16 A. Yes.

11:06:46 17 Q. And you've probably been prescribing

11:06:49 18 them, in one form or another, since you were a

11:06:52 19 resident; is that right?

11:06:52 20 A. Yes.

11:06:53 21 Q. Maybe even before, if you were allowed

11:06:56 22 to, true?

11:06:57 23 A. Internship, residency.

11:07:01 24 Q. Okay. And are you familiar in general

11:07:14 25 with the potential risks and side-effects of digoxin

Reynolds M. Delgado III, M.D.

Page 34

11:07:19 1 products?

11:07:20 2 A. Yes.

11:07:25 3 Q. Now, let's take a patient like Mimi

11:07:30 4 Rivera-Vega, who had heart failure for at least back

11:07:36 5 to 2002, maybe before, okay?

11:07:39 6 A. Yes.

11:07:39 7 Q. And let's first define: In this medical

11:07:45 8 record that I have from your office, I think the

11:07:48 9 first visits are in 2002. Did you see her before

11:07:52 10 2002?

11:07:53 11 A. Not that I know of.

11:07:54 12 Q. Did she have heart failure in 2002?

11:07:58 13 A. Yes.

11:07:58 14 Q. And there are various strategies, if you

11:08:08 15 will, that cardiologists employ in treating

11:08:13 16 heart-failure patients, are there not?

11:08:15 17 A. Yes.

11:08:15 18 Q. Is there any way that you can

11:08:18 19 characterize for me what the strategy was for Mimi

11:08:23 20 Rivera-Vega from, say, 2002 to 2005?

11:08:28 21 A. Medical management.

11:08:35 22 Q. Okay. Well, I mean, in the old days, it

11:08:40 23 used to be digoxin and maybe a diuretic, were the

11:08:45 24 treatments; but in the more modern era, that have

11:08:50 25 evolved other medications that are employed,

Reynolds M. Delgado III, M.D.

Page 35

11:08:53 1 correct?

11:08:53 2 A. Yes.

11:08:53 3 Q. So if you can characterize it, what  
11:08:56 4 philosophy do you bring to bear on management of  
11:09:00 5 heart failure back in 2002 to 2004?

11:09:05 6 A. "Medical management" meaning standard of  
11:09:10 7 care, standard medical therapy --

11:09:12 8 Q. All right.

11:09:13 9 A. -- at the time.

11:09:14 10 Q. Well, let me jump to 2009, because it's  
11:09:17 11 fresh on my mind, but the new AHA/ACCF guidelines  
11:09:22 12 talk about the primary therapy being something  
11:09:29 13 like amiodarone, an ACE inhibitor, a diuretic and  
11:09:34 14 one other -- I can't remember if it's a beta  
11:09:37 15 blocker; and then in some patients, they'll use  
11:09:41 16 digoxin for various purposes.

11:09:44 17 I mean, is that the kind of therapy  
11:09:45 18 that you subscribe to?

11:09:47 19 A. That's a reasonable way of putting it, I  
11:09:55 20 guess.

11:09:55 21 Q. Okay. A gross and reasonable way?

11:09:57 22 A. A gross way to put it, yes.

11:09:59 23 Q. All right. Well, let me ask it this  
11:10:02 24 way: What do you perceive the role of digoxin  
11:10:05 25 products to be in a patient like Mimi Rivera-Vega

Reynolds M. Delgado III, M.D.

Page 36

11:10:09 1 back in 2002 to 2004, for example?

11:10:15 2 A. Primarily at that time, it was known  
11:10:20 3 that the drug could improve symptoms, but more  
11:10:24 4 importantly, that if the drug were to be withdrawn,  
11:10:27 5 the symptoms could worsen.

11:10:31 6 Q. Okay. And historically, it was to  
11:10:34 7 improve symptoms and try to keep people out of the  
11:10:37 8 hospital with acute exacerbations of heart failure,  
11:10:44 9 correct?

11:10:44 10 A. Yes.

11:10:44 11 Q. And I think even the original DIG trial  
11:10:54 12 papers that led to that Exhibit 17 you've got there  
11:10:59 13 showed that that was one of the benefits of digoxin,  
11:11:05 14 correct?

11:11:05 15 A. Yes.

11:11:05 16 Q. And in your heart-failure patients,  
11:11:17 17 what -- do you use loading doses?

11:11:19 18 A. It depends.

11:11:20 19 Q. All right. Well, let me skip, then.

11:11:22 20 What is your typical maintenance  
11:11:25 21 dose of digoxin in heart-failure patients?

11:11:29 22 A. That depends on weight and renal  
11:11:34 23 function.

11:11:34 24 Q. I'm sorry, it depends on what?

11:11:35 25 A. It depends on weight and renal function.

Reynolds M. Delgado III, M.D.

Page 37

11:11:38 1 Q. When you say "weight," are you talking  
11:11:39 2 about muscle mass or gross weight?

11:11:47 3 A. Overall weight.

11:11:48 4 Q. If the patient is obese, do you tend to  
11:11:50 5 use a higher dose or a lower dose?

11:11:56 6 A. Tend to use higher.

11:11:57 7 Q. And then, of course, you're tempering  
11:12:05 8 that by whatever the renal function is, correct?

11:12:08 9 A. Yes.

11:12:08 10 Q. Are you aware of any medical literature  
11:12:11 11 that says that digoxin causes renal failure?

11:12:22 12 A. Not that I know of.

11:12:28 13 Q. In fact, what the product labels and the  
11:12:31 14 literature say is that the dose should be managed  
11:12:37 15 based on the patient's renal function, correct?

11:12:42 16 A. Yes.

11:12:42 17 Q. Because impaired renal function  
11:12:46 18 increases the risk of digoxin toxicity, correct?

11:12:50 19 A. Yes.

11:12:50 20 Q. When you were in internship and  
11:13:02 21 residency, was the .50 digoxin dose still  
11:13:08 22 commercially available?

11:13:09 23 A. Not that I remember.

11:13:10 24 Q. Are there patients that you manage --  
11:13:21 25 I'm sorry, let me withdraw that.

Reynolds M. Delgado III, M.D.

Page 38

11:13:22 1 Do you manage any patients who have  
11:13:26 2 atrial fibrillation without heart failure?

11:13:29 3 A. Yes.

11:13:29 4 Q. In your a-fib patients who don't have  
11:13:35 5 heart failure, what is the maximum dose that you  
11:13:42 6 prescribe on a daily basis for any of those  
11:13:45 7 patients?

11:13:46 8 A. That depends. In that population of  
11:13:52 9 patients, you often use IV Regonol, and the dose is  
11:13:58 10 tailored to what we call rate control or control of  
11:14:02 11 their heart rate.

11:14:03 12 Q. Sure.

11:14:04 13 But are there patients in your own  
11:14:06 14 population -- and I'm not going to ask for names or  
11:14:09 15 anything. But in your own patient population, are  
11:14:12 16 there patients who get as much as .50 milligrams a  
11:14:16 17 day?

11:14:17 18 A. To rate-control, yes.

11:14:21 19 Q. Okay. Are there any of your patients  
11:14:22 20 who get more than .50 per day?

11:14:27 21 A. Occasionally.

11:14:28 22 Q. In your patients who get .50 per day, do  
11:14:34 23 you typically split them into two .250-milligram  
11:14:42 24 doses?

11:14:46 25 A. No.

Reynolds M. Delgado III, M.D.

Page 39

11:14:46 1 Q. Now, let's go back to your heart-failure  
11:14:49 2 population. What -- of your patient population,  
11:14:54 3 what's the largest dose that you prescribe your  
11:14:59 4 heart-failure patients per day?

11:15:02 5 A. Again, it depends on those factors; but  
11:15:11 6 the largest, in general, that I use is .25 a day.

11:15:17 7 Q. Okay. And would I be correct in  
11:15:25 8 assuming that your patients who are on .50 per day  
11:15:31 9 in your atrial fibrillation population don't  
11:15:36 10 necessarily all become digoxin-toxic?

11:15:42 11 A. No. As a point of clarification,  
11:15:44 12 they're not on .50 every day. .50 -- or .5 may be  
11:15:52 13 used one day as an acute method to rate-control a  
11:15:57 14 patient --

11:15:58 15 Q. Okay.

11:15:58 16 A. -- to get their rate within range.

11:16:00 17 Q. Okay. But even on those days they  
11:16:02 18 get .50, or if they need it on consecutive days for  
11:16:07 19 rate control, they don't all become digoxin-toxic,  
11:16:09 20 do they?

11:16:10 21 A. No.

11:16:10 22 Q. And do you have -- I've asked you about  
11:16:15 23 the a-fibs and the heart failures. Do you have  
11:16:17 24 patients who have both?

11:16:18 25 A. Yes.



Reynolds M. Delgado III, M.D.

Page 40

11:16:18 1 Q. And I assume that they could have doses  
11:16:26 2 that are -- that vary considerably, based on their  
11:16:29 3 rate control and their heart-failure symptoms,  
11:16:32 4 right?

11:16:33 5 A. Correct.

11:16:33 6 Q. Does chronic hypertension ultimately  
11:16:44 7 have an adverse impact on kidney function?

11:16:47 8 A. In some patients.

11:16:49 9 Q. Does obesity have an adverse impact on  
11:16:54 10 kidney function?

11:16:56 11 A. Not specifically.

11:16:57 12 Q. Does heart failure, chronic heart  
11:17:01 13 failure, have an adverse impact on kidney function?

11:17:05 14 A. In some patients.

11:17:06 15 Q. All right. You've told me about  
11:17:16 16 managing atrial fibrillation rates, or the rates in  
11:17:20 17 atrial fibrillation patients, and symptom management  
11:17:23 18 in heart failure.

11:17:24 19 When you give digoxin products, do  
11:17:26 20 you manage to a certain serum digoxin concentration  
11:17:33 21 number?

11:17:33 22 A. No. No.

11:17:39 23 Q. So, hypothetically, if a heart-failure  
11:17:42 24 patient comes in and they're consistently at .1  
11:17:48 25 or .2 on their SDC, do you classify them as

Reynolds M. Delgado III, M.D.

Page 41

11:17:53 1 subtherapeutic and try to up their dose?

11:17:58 2 A. No.

11:17:58 3 Q. And I assume, when you say "no," it's  
11:18:01 4 because you are managing to symptom-control, not a  
11:18:06 5 lab number, right?

11:18:07 6 A. Correct.

11:18:07 7 Q. Do you know what the St. Luke's lab's  
11:18:28 8 typical range is for digoxin concentrations?

11:18:36 9 A. I believe it is 1 to 2, I believe.

11:18:46 10 Q. Or .8 to 2, something in there?

11:18:50 11 A. Yes.

11:18:50 12 Q. Yes?

11:18:51 13 A. Yes.

11:18:51 14 Q. All right. If a patient comes in and  
11:18:53 15 they're at 2.5 but are not appearing to be  
11:18:59 16 digoxin-toxic, by whatever measures you use, do you  
11:19:03 17 necessarily drop down their dose?

11:19:07 18 A. I can't answer that, because it's  
11:19:09 19 hypothetical. The problem is that you wouldn't  
11:19:11 20 order the dig level in a patient unless you  
11:19:17 21 suspected digoxin toxicity.

11:19:27 22 Q. Okay. How do you define or diagnose  
11:19:31 23 digoxin toxicity in your own practice?

11:19:41 24 A. It is a constellation of symptoms and  
11:19:45 25 often a diagnosis of exclusion, so it's a

Reynolds M. Delgado III, M.D.

Page 42

11:19:48 1 complicated thought process that we necessarily go  
11:19:53 2 through to bring that into your differential.

11:19:58 3 Q. Are you done with your answer?

11:20:00 4 A. Yes.

11:20:01 5 Q. Okay. I don't want to cut you off.

11:20:04 6 What role does the serum digoxin  
11:20:06 7 concentration play in your analysis of whether a  
11:20:10 8 patient is digoxin-toxic or not?

11:20:18 9 A. Again, it's a hypothetical question  
11:20:25 10 because the level would not be checked unless you  
11:20:28 11 thought the patient was digoxin-toxic; so you're  
11:20:34 12 asking me to answer a question in retrospect, which  
11:20:37 13 is tough to do.

11:20:38 14 Q. Well, do you ever draw levels just for  
11:20:40 15 baseline purposes?

11:20:41 16 A. No.

11:20:41 17 Q. Do they do that in hospital, sometimes?

11:20:46 18 A. No.

11:20:47 19 Q. Well, if you believe -- if you, as a  
11:20:57 20 clinician, are entertaining in your mind digoxin  
11:21:02 21 toxicity in a differential diagnosis and you order a  
11:21:06 22 digoxin level and it comes back at .5, what weight  
11:21:14 23 do you give that level when you're assessing whether  
11:21:17 24 you think it's digoxin toxicity?

11:21:20 25 A. I would say a moderate amount of weight.

Reynolds M. Delgado III, M.D.

Page 43

11:21:24 1 Q. All right. And then what role in your  
11:21:27 2 practice does the electrocardiogram play in  
11:21:31 3 diagnosing digoxin toxicity?

11:21:39 4 A. A less amount of weight than that.

11:21:41 5 Q. Does digoxin toxicity have an ICD  
11:21:45 6 diagnosis code?

11:21:47 7 A. I don't know.

11:21:48 8 Q. Is digoxin toxicity one of the most  
11:22:00 9 common adverse drug reactions?

11:22:07 10 A. No. Not until recently.

11:22:11 11 Q. Does digoxin toxicity occur with tablets  
11:22:16 12 that are in the proper dose range?

11:22:20 13 A. In my experience, very rarely.

11:22:21 14 Q. How many times have you diagnosed  
11:22:27 15 digoxin toxicity in your career?

11:22:32 16 A. That's a hard question to answer because  
11:22:44 17 digoxin toxicity is less a diagnosis than it is a  
11:22:51 18 symptom or sign.

11:22:53 19 It's not necessarily something that  
11:22:55 20 you would use as a diagnosis unless you are planning  
11:22:58 21 on a specific treatment, for example, using an FAB  
11:23:03 22 fragment to -- monoclonal antibody drug to treat the  
11:23:10 23 digoxin toxicity syndrome; for example, polymorphic  
11:23:13 24 v-tach or something.

11:23:17 25 Q. Well, in those instances when you have

Reynolds M. Delgado III, M.D.

Page 44

11:23:19 1 diagnosed digoxin toxicity, did you assume that  
11:23:24 2 whatever tablets your patient was taking were  
11:23:30 3 somehow different from their labeled dose?

11:23:34 4 A. I never made that assumption until it  
11:23:37 5 was disclosed.

11:23:39 6 Q. What do you mean, "disclosed"?

11:23:41 7 A. When the warnings came out.

11:23:43 8 Q. What warnings?

11:23:44 9 A. The warnings came from our hospital,  
11:23:48 10 St. Luke's Hospital, and from local pharmacies,  
11:23:52 11 that --

11:23:52 12 Q. Are you talking about the Digitek  
11:23:54 13 recall?

11:23:55 14 A. -- that we should stop patients from  
11:23:58 15 taking Digitek, yes.

11:23:59 16 Q. Okay. So you're talking about the  
11:24:01 17 April 25th, 2008, recall?

11:24:02 18 A. Correct.

11:24:03 19 Q. All right. But if in 2002, 2003, 2004,  
11:24:09 20 et cetera, your patients demonstrated what you  
11:24:12 21 thought was signs or symptoms of digoxin toxicity,  
11:24:17 22 you didn't order some investigation into the potency  
11:24:21 23 of their tablets, did you?

11:24:22 24 A. No.

11:24:23 25 Q. People can get digoxin-toxic for many

Reynolds M. Delgado III, M.D.

Page 45

11:24:28 1 reasons, correct?

11:24:28 2 A. Yes.

11:24:35 3 Q. All right. So, for example, there are  
11:24:38 4 certain other pharmaceutical products that patients  
11:24:42 5 might be taking for their heart that could increase  
11:24:47 6 the risk of digoxin toxicity because they decrease  
11:24:51 7 renal clearance, correct?

11:24:53 8 A. Yes.

11:24:54 9 Q. So, for example, amiodarone is known to  
11:24:59 10 decrease renal clearance, Coreg is known to decrease  
11:25:04 11 renal clearance; and concomitantly taking either of  
11:25:07 12 those drugs with digoxin could increase the risk of  
11:25:10 13 toxicity, correct?

11:25:11 14 A. I have to say no because the way you're  
11:25:19 15 premising that question is wrong.

11:25:21 16 Q. Okay. What's wrong with my premise?

11:25:23 17 A. The amiodarone does not have that effect  
11:25:28 18 in increasing the risk of digitalis toxicity.

11:25:33 19 Q. Isn't there a chart in Braunwald's  
11:25:36 20 textbook that says it does?

11:25:38 21 A. The way you stated it is wrong. You  
11:25:41 22 said that it decreases renal -- I forgot what you  
11:25:45 23 said.

11:25:45 24 Q. Clearance, I think.

11:25:46 25 A. Clearance. That's not correct.

Reynolds M. Delgado III, M.D.

Page 46

11:25:49 1 Q. Well, okay. Then let me go back to  
11:25:51 2 square one.

11:25:52 3 Is amiodarone, through whatever  
11:25:56 4 mechanism, known to increase the risk of digoxin  
11:25:59 5 toxicity?

11:25:59 6 A. Yes.

11:26:00 7 Q. All right. And if a patient, for  
11:26:04 8 whatever reason, has acute renal failure or chronic  
11:26:08 9 renal failure, they can get digoxin-toxic because of  
11:26:11 10 that, correct?

11:26:12 11 A. Yes.

11:26:13 12 Q. Even if their pharmaceutical product is  
11:26:16 13 appropriately labeled and appropriately dosed,  
11:26:19 14 correct?

11:26:20 15 A. Yes.

11:26:21 16 Q. All right. So just because somebody  
11:26:30 17 manifests the signs or symptoms of digoxin toxicity  
11:26:33 18 does not automatically mean that they have  
11:26:35 19 inappropriately dosed digoxin product, correct?

11:26:40 20 A. I'm sorry. Repeat that.

11:26:48 21 Q. That's fine.

11:26:50 22 If a patient comes into your  
11:26:53 23 hospitals or your office and you believe, for  
11:26:56 24 whatever reason, that they are demonstrating signs  
11:26:59 25 or symptoms of digoxin toxicity, there's a number of

Reynolds M. Delgado III, M.D.

Page 47

11:27:05 1 things you're going to do for them, correct?

11:27:08 2 A. Yes.

11:27:08 3 Q. One is going to be you're going to order

11:27:11 4 a serum digoxin concentration, correct?

11:27:13 5 A. Perhaps.

11:27:15 6 Q. All right. You might order an

11:27:21 7 electrocardiogram?

11:27:22 8 A. Yes.

11:27:22 9 Q. You're likely to order a chemistry panel

11:27:25 10 to look at their electrolytes and their renal

11:27:30 11 function, correct?

11:27:30 12 A. Yes.

11:27:31 13 Q. So you're going to do an investigation

11:27:36 14 to see if you can understand why they're having

11:27:40 15 whatever these signs and symptoms are, correct?

11:27:42 16 A. Yes.

11:27:42 17 Q. In order to make an appropriate

11:27:44 18 diagnosis of what the problem might be?

11:27:47 19 A. Yes.

11:27:47 20 Q. And if it turns out to be some

11:27:54 21 electrolyte abnormality, you're going to try to

11:27:58 22 correct that, correct?

11:28:01 23 A. Yes.

11:28:01 24 Q. All right. So, in other words, if a

11:28:03 25 patient has these signs and symptoms, you want to



Reynolds M. Delgado III, M.D.

Page 48

11:28:07 1 get to the bottom of what the problem really is,  
11:28:09 2 correct?

11:28:10 3 A. Yes.

11:28:10 4 Q. You don't just assume that it's a  
11:28:12 5 defective pharmaceutical product, right?

11:28:13 6 A. Correct.

11:28:14 7 Q. Okay. Is there any one serum digoxin  
11:28:25 8 concentration level that is, per se, toxic?

11:28:30 9 A. Depends on the patient.

11:28:40 10 Q. Have you ever in your career encountered  
11:28:45 11 a circumstance in which a digoxin level of less than  
11:28:48 12 4 was fatal?

11:28:52 13 A. The digoxin level at a snapshot in time  
11:29:02 14 is not a cause of fatality.

11:29:05 15 Q. All right. I understand that. But if  
11:29:07 16 you're concerned about digoxin toxicity and in the  
11:29:11 17 workup you order an SDC and that patient happens to  
11:29:16 18 die in a short time in relation to this incident,  
11:29:22 19 have you ever encountered a circumstance in your own  
11:29:25 20 practice where they had a serum digoxin  
11:29:30 21 concentration less than 4, but you believe that they  
11:29:35 22 died as a result of digoxin toxicity?

11:29:39 23 A. Not that I can remember.

11:29:41 24 Q. If you're going to draw a serum digoxin  
11:30:10 25 concentration, is it true that in order to

Reynolds M. Delgado III, M.D.

Page 49

11:30:15 1 accurately get the level, it should be drawn six to  
11:30:20 2 eight hours after the last dose?

11:30:22 3 A. Yes.

11:30:22 4 Q. Have you ever made a report to the FDA  
11:30:51 5 of an adverse drug reaction for any drug?

11:30:54 6 A. Yes.

11:30:56 7 Q. What drugs?

11:30:58 8 A. I have been a principal investigator on  
11:31:06 9 pharmaceutical trials, drug trials, and one of my  
11:31:11 10 responsibilities in doing that was to submit SAEs  
11:31:18 11 and AEs to the FDA.

11:31:21 12 Q. How many times have you been an  
11:31:23 13 investigator on pharmaceutical trials?

11:31:24 14 A. Between five and ten, perhaps.

11:31:30 15 Q. Are you at liberty to tell me what those  
11:31:33 16 products were?

11:31:35 17 A. I honestly don't know, to be honest.

11:31:38 18 Q. Okay.

11:31:38 19 A. It's so complicated, what the FDA rules  
11:31:42 20 are regarding those trials.

11:31:44 21 Q. Okay. Have you ever made an adverse  
11:31:51 22 reaction report regarding a digoxin product?

11:32:00 23 A. No.

11:32:00 24 Q. So I assume you never made any adverse  
11:32:03 25 event reports regarding Mimi Rivera-Vega?

Reynolds M. Delgado III, M.D.

Page 50

11:32:06 1 A. Correct.

11:32:06 2 Q. Do you remember when you learned about  
11:32:15 3 the Digitek recall?

11:32:17 4 A. Roughly, April time frame of 2008.

11:32:23 5 Q. All right. After the Digitek recall,  
11:32:28 6 did you or your colleagues -- let me withdraw that  
11:32:34 7 question. That was bad.

11:32:36 8 Around the time of the Digitek  
11:32:38 9 recall, did you participate in any meetings with  
11:32:41 10 your cardiology colleagues or the St. Luke's  
11:32:45 11 Hospital pharmacy to discuss the recall and any  
11:32:50 12 ramifications of the recall, whether those  
11:32:54 13 ramifications had to do with your supply of digoxin  
11:32:58 14 or patient care or anything else?

11:33:00 15 A. No.

11:33:01 16 Q. Did you have -- you or your office have  
11:33:14 17 separate communication with patients regarding the  
11:33:20 18 Digitek recall?

11:33:21 19 A. Yes.

11:33:21 20 Q. What communication -- I'm sorry.

11:33:28 21 Was it in writing?

11:33:29 22 A. In some cases.

11:33:31 23 Q. What communication did you have?

11:33:33 24 A. Most commonly, patients would call us,  
11:33:42 25 asking about it, and we would tell them to stop the

Reynolds M. Delgado III, M.D.

Page 51

11:33:46 1 Digitek and write them a new prescription for  
11:33:49 2 another brand of digoxin.

11:33:53 3 Often, it would be done during a  
11:33:56 4 clinic visit, face to face. And then in other  
11:33:59 5 circumstances, in the normal course of going through  
11:34:02 6 charts, we'd find someone who was on the drug and  
11:34:05 7 we'd either send them a letter or call them --

11:34:09 8 Q. Okay.

11:34:09 9 A. -- or notify them.

11:34:11 10 Q. Okay. Now, I don't know how many  
11:34:12 11 patients you had, but how would you and your office  
11:34:15 12 staff know who was taking Digitek, who was taking  
11:34:21 13 Lanoxin, who was taking Jerome Stevens  
11:34:25 14 Pharmaceuticals' product, who was taking Caraco's  
11:34:27 15 product, et cetera?

11:34:29 16 A. It's difficult, and it was obvious in  
11:34:35 17 some cases. It was written in the chart as  
11:34:41 18 "Digitek," and in cases where patients would bring  
11:34:44 19 in their pill bottles and you would see the specific  
11:34:48 20 name. But it's difficult.

11:34:50 21 Q. Okay. Did you ever -- have you ever  
11:34:59 22 taken a Digitek tablet and measured it with a  
11:35:02 23 micrometer?

11:35:03 24 A. No.

11:35:03 25 Q. Have you ever weighed one on a scale?

Reynolds M. Delgado III, M.D.

Page 52

11:35:05 1 A. No.

11:35:05 2 Q. Have you ever sent any Digitek tablets

11:35:09 3 to a laboratory for potency or content uniformity

11:35:14 4 analysis?

11:35:15 5 A. No.

11:35:15 6 Q. Have you ever talked with anyone at

11:35:21 7 Actavis or Mylan about the recall?

11:35:24 8 A. No.

11:35:24 9 Q. Okay. Let's change gears again here.

11:35:43 10 MR. WILLIAMSON: A good time for a

11:35:45 11 break?

11:35:46 12 MR. MORIARTY: I'm sorry?

11:35:47 13 MR. WILLIAMSON: Good time for a

11:35:48 14 break, if you're changing gears?

11:35:50 15 MR. MORIARTY: Sure. We can break

11:35:52 16 whenever you want.

11:35:53 17 (Recess taken, 11:35 a.m. to

11:49:00 18 11:49 a.m.)

11:49:00 19 BY MR. MORIARTY:

11:49:02 20 Q. All right, Doctor. You know, give me a

11:49:09 21 break and I find something else to ask you before I

11:49:11 22 do change gears.

11:49:13 23 First of all, I was asking you

11:49:15 24 earlier on about medical records in general. When

11:49:18 25 you see a patient and you're just taking a history

Reynolds M. Delgado III, M.D.

Page 53

11:49:23 1 and doing a physical examination and it's some sort  
11:49:30 2 of an acute illness visit, I assume that, in your  
11:49:36 3 mind, you're at least going through that  
11:49:38 4 differential diagnosis process?

11:49:43 5 A. Yes.

11:49:44 6 Q. And then either as reflected in your  
11:49:46 7 plan or possibly reflected right in the chart would  
11:49:50 8 be the differential diagnosis or the possible  
11:49:56 9 diagnosis?

11:49:57 10 A. Yes.

11:49:57 11 Q. And then ultimately when you come to a  
11:49:59 12 diagnosis, you chart that in your records?

11:50:03 13 A. Yes.

11:50:04 14 Q. So that the plan for treating the  
11:50:08 15 diagnosis takes off from that point, right?

11:50:11 16 A. Yes.

11:50:12 17 Q. Okay. Now, I was asking you some  
11:50:16 18 questions earlier about how many of your patients  
11:50:19 19 had had digoxin toxicity, things of that nature. In  
11:50:27 20 your career as a cardiologist, have you ever  
11:50:31 21 diagnosed digoxin toxicity as a cause of a patient's  
11:50:35 22 death?

11:50:36 23 A. Not that I can remember.

11:50:44 24 Q. Have you ever diagnosed digoxin failure,  
11:50:50 25 if you will, subtherapeutic digoxin, as a cause of

Reynolds M. Delgado III, M.D.

Page 54

11:50:57 1 somebody's death?

11:50:58 2 A. No.

11:50:58 3 Q. Have you ever diagnosed that somebody  
11:51:01 4 needed a heart transplant because of either digoxin  
11:51:06 5 toxicity or digoxin failure?

11:51:09 6 A. No.

11:51:14 7 Q. All right. Let's talk about Mimi for a  
11:51:22 8 little bit.

11:51:24 9 Do you call her diagnosis postpartum  
11:51:28 10 cardiomyopathy or peripartum cardiomyopathy?

11:51:37 11 A. You can use either term.

11:51:39 12 Q. Do you, when you're talking with your  
11:51:42 13 colleagues, call it PPCM?

11:51:44 14 A. No. In general, I would say nonischemic  
11:51:50 15 cardiomyopathy.

11:51:51 16 Q. NICM?

11:51:54 17 A. Correct.

11:51:55 18 Q. It may even be easier for me to use the  
11:51:58 19 words than those abbreviations, because I'm bound to  
11:52:03 20 mess that up.

11:52:03 21 When you were treating Mimi  
11:52:07 22 Rivera-Vega, was she ever enrolled in any clinical  
11:52:10 23 trials?

11:52:23 24 A. I can't remember.

11:52:23 25 Q. Would your -- let's assume she was

Reynolds M. Delgado III, M.D.

Page 55

11:52:26 1 enrolled in a clinical trial. Would there be a  
11:52:28 2 separate file for her in the clinical trial folders?

11:52:34 3 A. If she was, yes. I just can't remember  
11:52:41 4 if she was.

11:52:42 5 Q. So, for example, you may have a nurse  
11:52:43 6 who's your research coordinator, and they may have a  
11:52:46 7 file drawer of the 50 patients enrolled in the  
11:52:49 8 whatever trial; there would be a folder for Mimi in  
11:52:52 9 there?

11:52:52 10 A. Correct.

11:52:53 11 Q. Okay. What would you have to do at your  
11:52:56 12 office to determine whether she was ever enrolled in  
11:53:07 13 any clinical trials?

11:53:09 14 A. I would have to communicate with the  
11:53:12 15 cardiology research department in Texas Heart  
11:53:15 16 Institute.

11:53:15 17 Q. Okay. I'm sorry to put that burden on  
11:53:17 18 you, but I'd like you to do that, if you could,  
11:53:19 19 because we may have to seek those records, if  
11:53:26 20 appropriate --

11:53:26 21 A. Yes.

11:53:27 22 Q. -- okay?

11:53:27 23 A. Yes.

11:53:27 24 Q. And then all you have to do is let  
11:53:29 25 Mr. Williamson know, and he'll let me know, okay?



Reynolds M. Delgado III, M.D.

Page 56

11:53:33 1 A. Yes.

11:53:33 2 Q. And if you encounter anything in your  
11:53:35 3 medical records that you brought today that leads  
11:53:37 4 you to think that she was involved in a trial, let  
11:53:40 5 me know, okay?

11:53:41 6 A. Yes.

11:53:45 7 THE WITNESS: Can I get a notepad,  
11:53:47 8 just to make a note for myself?

11:53:49 9 MR. MORIARTY: Sure.

11:53:52 10 THE WITNESS: Sorry.

11:53:53 11 MR. WILLIAMSON: Got a pen?

11:54:03 12 BY MR. MORIARTY:

11:54:03 13 Q. How many cases of postpartum  
11:54:06 14 cardiomyopathy do you think you have diagnosed and  
11:54:10 15 treated in your career?

11:54:11 16 A. Over a hundred.

11:54:12 17 Q. Have you ever published about postpartum  
11:54:20 18 cardiomyopathy?

11:54:20 19 A. Not specifically about the syndrome.

11:54:23 20 Q. All right. Once the patient has it, is  
11:54:25 21 it addressed substantially differently than any  
11:54:31 22 other form of nonischemic cardiomyopathy?

11:54:36 23 A. No, not substantially differently.

11:54:38 24 Q. Okay. So for purposes of Mimi's case,  
11:54:43 25 the etiology or the timing of her heart failure is

Reynolds M. Delgado III, M.D.

Page 57

11:54:49 1 of some historical interest, but the treatment of it  
11:54:52 2 isn't substantially different from what you would do  
11:54:55 3 with other heart-failure patients, correct?

11:54:57 4 A. Correct.

11:54:57 5 Q. Do you know, though, who first diagnosed  
11:55:05 6 her with postpartum cardiomyopathy?

11:55:09 7 A. I don't remember.

11:55:09 8 Q. Do you know who treated her for that  
11:55:11 9 between 1996, when it reputedly began, and when you  
11:55:18 10 started seeing her in 2002?

11:55:19 11 A. I don't remember.

11:55:20 12 Q. Is there anything in your record that  
11:55:22 13 indicates how she came to you as a patient, whether  
11:55:27 14 by referral or directly?

11:55:32 15 A. I do know that I was taking care of her  
11:55:36 16 father as a patient, so I believe she was a direct  
11:55:41 17 referral, meaning --

11:55:42 18 Q. Sure.

11:55:43 19 A. -- she came to see me.

11:55:46 20 Q. Okay. If she was seeing another  
11:55:52 21 cardiologist, would you have -- would your office  
11:55:54 22 practice have routinely tried to obtain prior  
11:55:58 23 records?

11:55:59 24 A. Yes.

11:56:00 25 Q. All right. Now, in my copy of your

Reynolds M. Delgado III, M.D.

Page 58

11:56:02 1 office chart, there are no such records, but I know  
11:56:07 2 that sometimes doctors' offices do not duplicate the  
11:56:12 3 records of others, for whatever reason. Can you  
11:56:16 4 look in your purple binder there and see if there  
11:56:19 5 are prior records for treatment of postpartum  
11:56:24 6 cardiomyopathy before 2002?

11:56:41 7 (Witness reviews document.)

11:59:24 8 BY MR. MORIARTY:

11:59:24 9 Q. Finding anything there?

11:59:25 10 A. No, nothing.

11:59:26 11 Q. All right. Then let's move on.

11:59:42 12 Do you know anything about the level  
11:59:47 13 of her left ventricular function when she was first  
11:59:53 14 diagnosed, prior to coming to you?

11:59:56 15 A. No.

11:59:58 16 Q. Does postpartum cardiomyopathy have a  
12:00:08 17 high mortality rate?

12:00:09 18 A. Yes.

12:00:09 19 Q. Why?

12:00:10 20 A. It can lead to shock and multi-system  
12:00:21 21 organ failure early in its course.

12:00:23 22 Q. Okay. Did you say "multi-system organ  
12:00:25 23 failure"?

12:00:25 24 A. Yes.

12:00:26 25 Q. All right. Did you ever form any

Reynolds M. Delgado III, M.D.

Page 59

12:00:31 1 opinion to a medical probability about the cause of  
12:00:33 2 her postpartum cardiomyopathy?

12:00:35 3 A. You mean that she had a baby?

12:00:44 4 Q. Well, other than that.

12:00:47 5 A. No.

12:00:48 6 Q. Okay. I mean, do they even -- do your  
12:00:52 7 cardiology colleagues even know what the exact  
12:00:56 8 mechanisms are that relate the pregnancy to the  
12:01:00 9 postpartum cardiomyopathy?

12:01:03 10 A. Yes. It is mechanistically understood,  
12:01:10 11 to some degree, as a form of molecular mimicry in  
12:01:15 12 which modules which are antigens on the surface of  
12:01:19 13 cells of the baby are mixed with the mother, and the  
12:01:25 14 mother forms an auto antibody based on those auto  
12:01:30 15 antigens, which are similar in characteristic to  
12:01:32 16 antigens on our own heart muscle cells, and there's  
12:01:37 17 some mimicry and cross-reaction that occurs that  
12:01:39 18 leads to acute heart failure.

12:01:48 19 Q. Sounds remotely similar to what they  
12:01:51 20 figured out years and years ago about hemolytic  
12:01:54 21 disease of the newborn, correct, some sort of auto  
12:01:58 22 antibodies between mother and child?

12:02:02 23 A. I would say remotely. That's -- it's --  
12:02:06 24 that's a very different syndrome.

12:02:08 25 Q. Okay. So in your office records -- and

Reynolds M. Delgado III, M.D.

Page 60

12:02:23 1 I have a set that is --

12:02:31 2 MR. MORIARTY: Is that this other  
12:02:32 3 set?

12:02:33 4 MS. AHERN: Yeah.

12:02:33 5 BY MR. MORIARTY:

12:02:34 6 Q. I have a set of the office records from  
12:02:36 7 you that were produced in this case, and they have  
12:02:39 8 been Bates-stamped, okay? These numbers down here.  
12:02:46 9 So it might be easier for us to work off the same  
12:02:49 10 set, if possible.

12:02:50 11 A. Yes.

12:02:50 12 Q. And I put those in front of you. I'd  
12:02:54 13 like you to go to June 2002 and look at either your  
12:03:01 14 office note or the echocardiogram that you ordered,  
12:03:08 15 and tell me what the significance of her ejection  
12:03:15 16 fraction was.

12:03:16 17 MR. WILLIAMSON: Could you give me a  
12:03:18 18 Bates-stamp number?

12:03:19 19 MR. MORIARTY: Yes, I will, as soon  
12:03:21 20 as I can figure that out. I believe that it is --  
12:03:47 21 well, actually, I can't tell you.

12:03:55 22 A. I see an echocardiogram, 9/02, 9/11/02.

12:04:03 23 BY MR. MORIARTY:

12:04:03 24 Q. Okay. That's fine. What is it, then,  
12:04:05 25 zero, or is it less than 20%?

Reynolds M. Delgado III, M.D.

Page 61

12:04:06 1 A. Less than 20% ejection fraction.

12:04:10 2 Q. Oh. 9/11/02.

12:04:12 3 MR. MORIARTY: Jimmy, that would be

12:04:14 4 MVDCA:0096.

12:04:18 5 MR. WILLIAMSON: Thank you.

12:04:19 6 MR. MORIARTY: Okay.

12:04:19 7 BY MR. MORIARTY:

12:04:19 8 Q. What's the significance of that ejection

12:04:21 9 fraction?

12:04:22 10 A. Significance to?

12:04:32 11 Q. Her condition, her function, her heart

12:04:35 12 function, her prognosis. What is its significance

12:04:41 13 to you, as a cardiologist?

12:04:43 14 A. It indicates to me that she has

12:04:49 15 postpartum -- or nonischemic cardiomyopathy.

12:04:56 16 Q. Is it severe?

12:04:57 17 A. Is heart failure severe, you mean?

12:05:02 18 Q. Does the function of her heart, as

12:05:06 19 measured by the echocardiogram, indicate severe

12:05:12 20 postpartum cardiomyopathy or severe heart failure?

12:05:15 21 A. No.

12:05:16 22 Q. How would you characterize her heart

12:05:19 23 failure as of September of 2002?

12:05:23 24 A. Nonischemic cardiomyopathy.

12:05:32 25 Q. You don't characterize it as mild,

Reynolds M. Delgado III, M.D.

Page 62

12:05:34 1 moderate or severe?

12:05:35 2 A. The ejection fraction is severely  
12:05:42 3 impaired.

12:05:43 4 Q. Okay.

12:05:47 5 A. That has nothing to do with anything  
12:05:49 6 else.

12:05:50 7 Q. All right. And then back at  
12:06:03 8 page MVDCA:98, which is a few pages back from that  
12:06:06 9 echocardiogram -- no, I'm sorry, forward, towards  
12:06:09 10 the front of this. It's kind of an odd photocopied  
12:06:16 11 page, but it's an MVO2 exercise stress test report.

12:06:21 12 A. What was the number, again? I'm sorry.

12:06:22 13 Q. Well, my binder may be out of numeric  
12:06:26 14 order.

12:06:26 15 A. Yeah.

12:06:26 16 Q. So if you go back to the beginning of  
12:06:28 17 the binder, it's maybe six pages back.

12:06:36 18 A. Yes.

12:06:36 19 Q. All right. I assume you ordered this as  
12:06:38 20 some sort of baseline evaluation of her function,  
12:06:41 21 correct?

12:06:42 22 A. No.

12:06:43 23 Q. Why was this ordered?

12:06:44 24 A. This is a prognostic test.

12:06:49 25 Q. All right. And based on the results of

Reynolds M. Delgado III, M.D.

Page 63

12:06:53 1 this exercise stress test report, what prognostic  
12:06:57 2 information did it give you about her condition?

12:07:01 3 A. Good. Her prognosis is good, based on  
12:07:05 4 this, as of that date.

12:07:06 5 Q. And what do you mean by "good"?

12:07:09 6 A. The --

12:07:14 7 Q. And I assume everything is relative  
12:07:18 8 here, so what do you mean by "good"?

12:07:21 9 A. Yes. Excuse me for one second.

12:07:25 10 (Witness reviews document.)

12:07:29 11 A. It's not in the output of this report  
12:07:54 12 because at that time we weren't doing it, but now we  
12:07:58 13 do. We actually state the prognosis numbers  
12:08:02 14 specifically.

12:08:03 15 But to make a long story short, an  
12:08:07 16 MVO2 of 16.5 at that time with an RQ of .96  
12:08:13 17 indicates that her medium- and long-term prognosis  
12:08:16 18 is good. Her chances of dying are low.

12:08:20 19 BY MR. MORIARTY:

12:08:21 20 Q. Okay. But obviously it says her  
12:08:23 21 exercise tolerance is poor, correct, the report  
12:08:28 22 itself?

12:08:29 23 A. Do you see a --

12:08:32 24 Q. Page 98, MVDCA:98. It should be the  
12:08:39 25 other direction, Doctor. The other direction.



Reynolds M. Delgado III, M.D.

Page 64

12:08:44 1 A. This way?

12:08:44 2 Q. Yes. My copy is, I think, one back.

12:08:50 3 It's a very unusual copy. Looks like this. Can you

12:08:56 4 see that?

12:08:57 5 A. Oh, yeah. Okay.

12:08:59 6 Q. Yeah. Right in the middle, it says,

12:09:03 7 "Exercise tolerance, poor." You see that, under

12:09:09 8 "Interpretation"?

12:09:10 9 A. Yes.

12:09:10 10 Q. Okay.

12:09:11 11 A. Yes.

12:09:11 12 Q. So what this is telling you is that her

12:09:17 13 short-term mortality is not an overwhelming concern

12:09:22 14 from a cardiology standpoint, correct?

12:09:24 15 A. Medium- and long-term.

12:09:27 16 Q. Okay. And "medium- and long-term"

12:09:30 17 meaning what, in your world?

12:09:31 18 A. Six months to five years.

12:09:34 19 Q. In order for her to have this good

12:09:39 20 prognosis, is she supposed to participate in any

12:09:42 21 particular therapies?

12:09:47 22 A. That is not specifically required. The

12:09:55 23 results and the ability of this test to

12:09:58 24 prognosticate are based on prior studies done.

12:10:04 25 Q. Prior what?

Reynolds M. Delgado III, M.D.

Page 65

12:10:05 1 A. Is based on prior studies done.

12:10:07 2 Q. Okay. But certainly, given the degree  
12:10:12 3 of her disease at that point, she's going to need  
12:10:14 4 medical management?

12:10:15 5 A. Yes.

12:10:16 6 Q. Okay. Did her ejection fraction or her  
12:10:21 7 left ventricular function ever improve?

12:10:28 8 A. No.

12:10:29 9 Q. In fact, they deteriorated, did they  
12:10:31 10 not?

12:10:32 11 A. No.

12:10:32 12 Q. Didn't she ultimately deteriorate to the  
12:10:36 13 point where she had no native heart function?

12:10:40 14 A. You said "ejection fraction," as I  
12:10:44 15 remember. I may have --

12:10:45 16 Q. I said "ejection fraction" and "left  
12:10:47 17 ventricular function."

12:10:48 18 A. Those are two different things.

12:10:50 19 Q. I understand that, but...

12:10:52 20 A. Yeah.

12:10:52 21 Q. Okay.

12:10:52 22 MR. WILLIAMSON: He -- I'm sure he  
12:10:54 23 can rephrase it.

12:10:56 24 MR. MORIARTY: That's fine.

12:10:57 25 THE WITNESS: Would you please just

Reynolds M. Delgado III, M.D.

Page 66

12:10:58 1 restate the question? I don't understand it.

12:11:01 2 BY MR. MORIARTY:

12:11:01 3 Q. Well, did her heart function overall  
12:11:03 4 deteriorate?

12:11:09 5 A. I'm not sure how to answer that, either.  
12:11:11 6 In February -- January-February '08, she went into  
12:11:17 7 cardiogenic shock and required placement of a  
12:11:22 8 defibrillator.

12:11:22 9 Q. Okay. Well, let me ask it this way  
12:11:24 10 because I'm looking at this, obviously, not as a  
12:11:26 11 cardiologist. I see Ms. Rivera-Vega going to an  
12:11:31 12 implantable cardiac defibrillator, and then an LVAD;  
12:11:40 13 she had home IV inotropic therapy. Are those  
12:11:46 14 indicators of deteriorating heart function?

12:11:49 15 A. The LVAD is.

12:11:52 16 Q. Why isn't the need for home IV inotropic  
12:11:57 17 therapy an indicator of deteriorating heart  
12:12:00 18 function?

12:12:00 19 A. Depends how you use it. In most cases,  
12:12:06 20 inotropic therapy, home IV inotropic therapy, is  
12:12:10 21 used as either palliative care or  
12:12:15 22 bridge-to-transplant. So it's not an indicator of  
12:12:19 23 worsening function; it's used to achieve a specific  
12:12:25 24 goal.

12:12:25 25 Q. Okay. In the population of patients who

Reynolds M. Delgado III, M.D.

Page 67

12:12:29 1 have the degree of heart disease that she had when  
12:12:34 2 you first saw her in 2002, what percentage of those  
12:12:39 3 patients are likely going to ultimately need  
12:12:44 4 bridge-to-transplant therapy or a transplant?

12:12:48 5 A. It widely depends on a number of  
12:12:52 6 factors.

12:12:54 7 Q. Give me a couple of the factors it  
12:12:56 8 depends on.

12:12:56 9 A. The key one is nonischemic  
12:13:01 10 cardiomyopathy. That is the key one, it being of a  
12:13:04 11 nonischemic etiology. The other key thing in her  
12:13:06 12 point -- to her favor was that she had postpartum  
12:13:09 13 cardiomyopathy.

12:13:09 14 Q. Okay.

12:13:12 15 A. Her age is another good factor.

12:13:14 16 Q. All right. So does that mean that there  
12:13:17 17 is a -- so in a patient population who had  
12:13:23 18 postpartum cardiomyopathy, nonischemic, who have her  
12:13:27 19 degree of function in 2002, what percentage of those  
12:13:30 20 are going to go on to need bridge-to-transplant  
12:13:34 21 therapy or a transplant?

12:13:35 22 A. That's the key, because it depends on  
12:13:38 23 when they develop the postpartum cardiomyopathy.  
12:13:42 24 The point being that postpartum cardiomyopathy has a  
12:13:45 25 high mortality because of an early death hazard, and

Reynolds M. Delgado III, M.D.

Page 68

12:13:48 1 if you pass that early death hazard, then your risk  
12:13:51 2 after that is very low.

12:13:52 3 Q. And what's the early phase?

12:13:55 4 A. First few weeks, postpartum.

12:14:00 5 Q. Okay. So once she gets out into 1997  
12:14:02 6 and beyond, she's not at a high mortality risk,  
12:14:08 7 correct?

12:14:08 8 A. Better stated, 1992 -- or, I'm sorry,  
12:14:12 9 2002, when I started seeing her.

12:14:14 10 Q. Sure. Okay.

12:14:15 11 But if she was diagnosed in '96 or  
12:14:19 12 had the onset of this disease in 1996, by the time  
12:14:23 13 she sees you, she's no longer in this high mortality  
12:14:27 14 risk category?

12:14:28 15 A. Yes.

12:14:29 16 Q. All right. Was she getting digoxin in  
12:14:37 17 19- -- I'm sorry, 2002?

12:14:39 18 A. I would have to look at the notes.

12:14:44 19 Q. All right. I'd like you to go to  
12:14:46 20 page 139, which is actually the first page of actual  
12:14:53 21 medical records in that binder. There's a couple of  
12:14:59 22 administrative pages you have to go by. Two back.  
12:15:03 23 No, right by your first -- you see that?

12:15:07 24 A. Yes.

12:15:07 25 Q. Okay. July 15th, 2002?

Reynolds M. Delgado III, M.D.

Page 69

12:15:12 1 A. Yes.

12:15:12 2 Q. It goes down on the left under

12:15:15 3 "Medications."

12:15:15 4 A. Yes.

12:15:16 5 Q. It says, "Digoxin, question mark,"

12:15:18 6 correct? You see that?

12:15:19 7 A. Yes.

12:15:20 8 Q. And that's actually part of the form, is

12:15:22 9 it not?

12:15:22 10 A. Yes.

12:15:22 11 Q. And it indicates .125 milligrams every

12:15:28 12 day?

12:15:28 13 A. Yes.

12:15:28 14 Q. Do you have any way to know what brand

12:15:37 15 of digoxin product she was getting at that point?

12:15:41 16 A. No.

12:15:41 17 Q. Okay. All right. I'm going to step

12:15:44 18 over there and ask you some questions about some

12:15:51 19 sheets, and I'll...

12:16:06 20 MR. MORIARTY: Here, Jimmy.

12:16:08 21 MR. WILLIAMSON: Is that my copy?

12:16:09 22 MR. MORIARTY: Yeah.

12:16:10 23 MR. WILLIAMSON: Thank you.

12:16:10 24 (Delgado Deposition Exhibit 1

12:16:11 25 marked.)

Reynolds M. Delgado III, M.D.

Page 70

12:16:11 1 BY MR. MORIARTY:

12:16:11 2 Q. I've had these marked as -- this one is  
12:16:14 3 called Delgado No. 1. All right.

12:16:18 4 Do you recognize this as a  
12:16:20 5 medication administration record form?

12:16:24 6 A. Yes.

12:16:24 7 Q. And I believe this is from St. Luke's  
12:16:27 8 Hospital in January of 2008, okay? There's no year  
12:16:35 9 on it --

12:16:36 10 A. Actually, it's '07.

12:16:38 11 Q. Oh, this is January of '07?

12:16:40 12 A. No, wait a minute. You may be right. I  
12:16:43 13 was looking at the 7 there. Yeah, you're right.

12:16:44 14 Q. I'm pretty sure this is 2008.

12:16:46 15 A. Correct.

12:16:47 16 Q. So down here, you see it says "Digoxin  
12:16:52 17 (Digitek)." Do you see that?

12:16:54 18 A. Yes.

12:17:00 19 Q. Now, at St. Luke's Hospital, do they  
12:17:03 20 code these MAR sheets to actually coincide with the  
12:17:11 21 brand that is being dispensed from the pharmacy?

12:17:17 22 A. I don't know.

12:17:21 23 Q. All right. Well, you know that there  
12:17:25 24 are a number of digoxin tablet brands available,  
12:17:29 25 correct?

Reynolds M. Delgado III, M.D.

Page 71

12:17:29 1 A. Correct.

12:17:29 2 (Delgado Deposition Exhibit 2

12:17:29 3 marked.)

12:17:30 4 BY MR. MORIARTY:

12:17:30 5 Q. Okay. So on Exhibit 2, which is from

12:17:39 6 February of 2008 at St. Luke's Hospital --

12:17:44 7 A. Right.

12:17:44 8 Q. -- here it says "Digoxin tablet

12:17:50 9 (Lanoxin)." Do you see that?

12:17:52 10 A. Yes.

12:17:52 11 Q. All right. Do you know whether, in

12:17:54 12 fact, at that point, she was getting the brand name

12:17:58 13 Lanoxin?

12:18:00 14 A. I would believe so, based on this. I

12:18:03 15 know that the hospital went back and forth between

12:18:07 16 different brands around this time. And when they

12:18:09 17 communicated to us that they had been using the

12:18:14 18 Digitek brand, that's what made me know that they

12:18:17 19 had been using that.

12:18:17 20 (Delgado Deposition Exhibit 3

12:18:17 21 marked.)

12:18:17 22 BY MR. MORIARTY:

12:18:17 23 Q. Okay. So we can ultimately confirm this

12:18:19 24 with the pharmacy, but I've got you here today. So

12:18:23 25 if I go to Exhibit 3, which is from February of



Reynolds M. Delgado III, M.D.

Page 72

12:18:30 1 2008, when she was back in St. Luke's, here it  
12:18:34 2 says -- on this medication record, it says "Digitek  
12:18:38 3 (Digoxin)," correct?  
12:18:42 4 A. Yes.  
12:18:42 5 Q. All right. And do you know whether or  
12:18:46 6 not, in fact, that's the Digitek brand that she was  
12:18:49 7 being administered while an inpatient at that point?  
12:18:52 8 A. Yes.  
12:18:52 9 Q. You think she was?  
12:18:55 10 A. Yes.  
12:18:55 11 (Delgado Deposition Exhibit 4  
12:18:55 12 marked.)  
12:18:55 13 BY MR. MORIARTY:  
12:18:55 14 Q. All right. So if I went through to  
12:18:57 15 Exhibit 4, this one, again, says "Digitek  
12:19:02 16 (Digoxin)." Do you see that?  
12:19:05 17 A. Yes.  
12:19:05 18 (Delgado Deposition Exhibit 5  
12:19:05 19 marked.)  
12:19:05 20 BY MR. MORIARTY:  
12:19:05 21 Q. And then on this one, which is April --  
12:19:17 22 I don't know why I even marked this one. Oh. At  
12:19:19 23 the top, it says "Digoxin (Digitek)." Do you see  
12:19:26 24 that?  
12:19:26 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 73

12:19:26 1 (Delgado Deposition Exhibit 6  
12:19:26 2 marked.)  
12:19:26 3 BY MR. MORIARTY:  
12:19:26 4 Q. And on Delgado Exhibit 6, which is from  
12:19:29 5 the summer of 2008, here it just says "Digoxin,"  
12:19:35 6 correct?  
12:19:36 7 A. Yes.  
12:19:36 8 Q. There's no brand indicated anywhere,  
12:19:39 9 right?  
12:19:39 10 A. Yes.  
12:19:39 11 Q. And, of course, we know by then, the  
12:19:42 12 Digitek had been recalled and shouldn't have been  
12:19:46 13 dispensed from the pharmacy at St. Luke's, right?  
12:19:49 14 A. Correct.  
12:19:49 15 Q. Do you know anything about when  
12:19:56 16 St. Luke's in-house pharmacy pulled Digitek from the  
12:20:02 17 availability to give to the floors?  
12:20:04 18 A. No, I'm not that in tune with how they  
12:20:10 19 run the pharmacy and the hospital. I just know that  
12:20:13 20 they communicated to us in approximately April the  
12:20:18 21 recall --  
12:20:18 22 Q. Okay.  
12:20:18 23 A. -- and that they had drug in the  
12:20:21 24 hospital that they were stopping.  
12:20:22 25 Q. Sure.

Reynolds M. Delgado III, M.D.

Page 74

12:20:25 1 Do you know whether St. Luke's  
12:20:26 2 pharmacy dispensed its Lanoxin products -- I'm  
12:20:31 3 sorry. Withdraw that question.

12:20:32 4 Do you know whether the St. Luke's  
12:20:35 5 pharmacy dispensed its digoxin products in bottles  
12:20:40 6 or in blister packs?

12:20:42 7 A. No. And it would depend. Some were IV,  
12:20:47 8 in fact, and some were a liquid form.

12:20:49 9 Q. Sure.

12:20:50 10 But when it was tablets, you don't  
12:20:52 11 know how -- in what format it was dispensed?

12:20:55 12 A. Correct.

12:20:55 13 Q. All right. So let's go back to this  
12:21:05 14 note I was asking you about, MVDCA:139. She was  
12:21:11 15 also on Prinivil, correct?

12:21:14 16 A. Yes.

12:21:14 17 Q. What is that?

12:21:15 18 A. It's an ACE inhibitor. A-C-E, capital.

12:21:18 19 Q. Is amiodarone an ACE inhibitor?

12:21:24 20 A. No.

12:21:24 21 Q. And then she was on furosemide. That's  
12:21:27 22 a diuretic, correct?

12:21:29 23 A. Yes.

12:21:29 24 Q. Is it potassium-sparing or  
12:21:33 25 nonpotassium-sparing?

Reynolds M. Delgado III, M.D.

Page 75

12:21:33 1 A. Nonpotassium-sparing.

12:21:36 2 Q. And what is spironolactone?

12:21:41 3 A. That is a diuretic as well.

12:21:43 4 Q. And the KCl, I assume, is potassium

12:21:48 5 chloride?

12:21:48 6 A. Yes.

12:21:48 7 Q. Why was she on potassium chloride?

12:21:51 8 A. To balance the loss of potassium from

12:21:55 9 the furosemide.

12:22:00 10 Q. I see up at the top under the "Problem"

12:22:04 11 list, it says, "Wants to have another pregnancy."

12:22:07 12 Do you see that?

12:22:07 13 A. Yes.

12:22:07 14 Q. And then way at the bottom under "Plan,"

12:22:11 15 "Advised against further pregnancy and for" --

12:22:16 16 A. "Permanent sterilization."

12:22:19 17 Q. Is that your handwriting, by the way?

12:22:20 18 A. Yes.

12:22:21 19 Q. Is that the advice you gave her back in

12:22:26 20 July of 2002?

12:22:27 21 A. Yes.

12:22:27 22 Q. And are you aware that that topic came

12:22:30 23 up again later in your office notes?

12:22:41 24 A. I don't remember --

12:22:44 25 Q. Well, if I told you --

Reynolds M. Delgado III, M.D.

Page 76

12:22:46 1 A. -- the number of times it came up. I  
12:22:49 2 just remember that it did come up, and that's what I  
12:22:52 3 always advise patients with this problem.

12:22:53 4 Q. So if I told you I saw a note about it  
12:22:55 5 on January 15th of '04, would you have any reason to  
12:22:59 6 disagree with me about that?

12:23:00 7 A. No.

12:23:00 8 Q. Do you know anything about what attempts  
12:23:06 9 Mimi and Scott were making in 2000 or 2001 to get  
12:23:11 10 pregnant again?

12:23:12 11 A. No.

12:23:13 12 Q. If they were going to a fertility clinic  
12:23:20 13 for things like Clomid, would you have advised  
12:23:27 14 against that?

12:23:28 15 A. Well, just as I say here, any patient  
12:23:36 16 with postpartum cardiomyopathy, I advise against  
12:23:40 17 subsequent pregnancies.

12:23:41 18 Q. All right. To what did you attribute  
12:23:45 19 her symptoms on July 15th, 2002?

12:23:47 20 A. Nonischemic cardiomyopathy.

12:24:16 21 Q. Okay. If you go forward in your chart  
12:24:39 22 to page MVDCA:101, it's about four pages ahead of  
12:24:48 23 where we just were. Maybe five pages.

12:24:59 24 A. Yes.

12:24:59 25 Q. What is this sheet?

Reynolds M. Delgado III, M.D.

Page 77

12:25:05 1 A. This is a report from a bioimpedance  
12:25:12 2 test.

12:25:13 3 Q. What's the significance of the test and  
12:25:14 4 the results for her?

12:25:21 5 A. This is a test that is generally used to  
12:25:36 6 determine volume status and is useful for  
12:25:40 7 determining systemic vascular resistance and  
12:25:43 8 managing hypertension and fluid volume.

12:25:47 9 Q. Okay. So what did this report tell you  
12:25:50 10 about her?

12:25:50 11 A. It told me that her volume status was  
12:25:53 12 okay, but that her systemic resistance was high.  
12:25:56 13 Her blood pressure is high.

12:25:58 14 Q. In other words, she was hypertensed?

12:26:01 15 A. Yes.

12:26:01 16 Q. And go back one page, please. This  
12:26:16 17 looks like an office visit, August 18th, 2002. Do  
12:26:19 18 you see that?

12:26:20 19 A. Yes.

12:26:20 20 Q. And under "Problem List," it says, "See  
12:26:24 21 rehab study for CHF." Does that mean you were going  
12:26:30 22 to perform a study or that she was going to be  
12:26:34 23 enrolled in a clinical study?

12:26:36 24 A. I'm sorry, which page are we?

12:26:38 25 Q. MVDCA:100.

Reynolds M. Delgado III, M.D.

Page 78

12:26:41 1 A. 100. Okay.

12:26:43 2 Q. Up in the "Problem List."

12:26:56 3 A. That was a study that was being done at  
12:27:00 4 the time, a clinical research trial.

12:27:05 5 Q. All right. So that's a possibility to  
12:27:06 6 look for something she may have been enrolled in?

12:27:08 7 A. Yes.

12:27:09 8 Q. So when we get up to page 128, which is  
12:27:23 9 a hemodynamic status report in January of 2003, it's  
12:27:34 10 MVDCA:128, this is a follow-up study to the one we  
12:27:43 11 were just talking about, correct?

12:27:44 12 A. Yes.

12:27:45 13 Q. And do you do this to see how she's  
12:27:48 14 responding to the treatment?

12:27:51 15 A. Yes.

12:27:51 16 Q. And in general, how was she responding  
12:27:54 17 to treatment at that time?

12:27:55 18 A. Blood pressure was a little lower.  
12:28:00 19 Volume status was a little lower.

12:28:03 20 Q. And then on the next page,  
12:28:11 21 page MVDCA:120, do you see at the bottom right under  
12:28:16 22 "Assessment: Hypertension, poor control"?

12:28:18 23 A. Yes.

12:28:18 24 Q. Was it frequently difficult to control  
12:28:22 25 her hypertension?

Reynolds M. Delgado III, M.D.

Page 79

12:28:24 1 A. Yes.

12:28:24 2 Q. Do you know why?

12:28:26 3 A. It is a good prognostic sign. It's an  
12:28:36 4 indicator of contractile reserve, a high contractile  
12:28:41 5 reserve. And a high SVR and a high blood pressure  
12:28:47 6 is actually a good -- good prognostic sign for heart  
12:28:50 7 failure, but...

12:28:54 8 Q. But it needs to be controlled?

12:28:55 9 A. Yes.

12:28:56 10 Q. And the fact that hers was poorly  
12:28:59 11 controlled means what? That it was either difficult  
12:29:02 12 to control or she wasn't compliant with her  
12:29:05 13 medications or she wasn't compliant with her diet?  
12:29:08 14 What does it tell you?

12:29:09 15 A. Really, I mean, all those are  
12:29:14 16 possibilities that play into it, but what it really  
12:29:17 17 tells me is that she's got a good prognosis.

12:29:24 18 Q. All right.

12:29:24 19 A. And it tells me to be more aggressive in  
12:29:28 20 my diagnosis.

12:29:29 21 Q. Okay. And on that date, she was still  
12:29:31 22 on .125 digoxin, correct?

12:29:36 23 A. Yes.

12:29:36 24 Q. And why .125?

12:29:39 25 A. I don't remember what the thinking was



Reynolds M. Delgado III, M.D.

Page 80

12:29:47 1 for picking that specific dose at that time.

12:29:49 2 Q. Well, was .125 adequate for whatever you  
12:29:55 3 were using it for?

12:29:56 4 A. Yes.

12:29:57 5 Q. Okay. If she was consistently  
12:30:08 6 taking .250 digoxin per day, do you believe it is  
12:30:13 7 likely that she would have reacted in ways that you  
12:30:16 8 could observe?

12:30:20 9 A. I don't understand.

12:30:24 10 Q. Sure.

12:30:27 11 The prescription you were writing  
12:30:31 12 and what she was taking was .125 milligrams a day,  
12:30:35 13 correct?

12:30:35 14 A. Yes.

12:30:35 15 Q. Regardless of which digoxin product she  
12:30:39 16 may have been using at the time, right?

12:30:41 17 A. Yes.

12:30:41 18 Q. But if, for some reason, she was taking  
12:30:46 19 double that every day, isn't it likely that she  
12:30:49 20 would have exhibited signs or symptoms that you  
12:30:54 21 would have been able to detect?

12:30:56 22 A. No.

12:30:57 23 Q. Why not?

12:30:58 24 A. .25 would still be an appropriate dose.

12:31:06 25 Q. Okay. So, in other words, if she was

Reynolds M. Delgado III, M.D.

Page 81

12:31:12 1 consistently taking double doses in this period of  
12:31:15 2 time, it wouldn't necessarily mean she was going to  
12:31:20 3 be digoxin-toxic, correct?

12:31:21 4 A. Yes.

12:31:21 5 Q. And it wouldn't necessarily mean that  
12:31:23 6 she would be medically harmed by the excess dose,  
12:31:28 7 correct?

12:31:28 8 A. Yes.

12:31:29 9 Q. All right. I want to jump ahead to  
12:31:43 10 December of 2004, and I will find that note and page  
12:31:50 11 number.

12:31:52 12 MR. WILLIAMSON: Can we go off the  
12:31:53 13 record for a second, since you're at a breaking  
12:31:56 14 point?

12:32:02 15 THE REPORTER: I'm sorry, off?

12:32:04 16 MR. MORIARTY: Sure.

12:32:18 17 (Recess taken, 12:32 p.m. to  
12:46:04 18 12:46 p.m.)

12:46:05 19 BY MR. MORIARTY:

12:46:06 20 Q. Have you ever sent Mr. Williamson or  
12:46:08 21 anyone in his office anything in writing regarding  
12:46:11 22 Mimi Rivera-Vega: letters, memos things of that  
12:46:17 23 nature?

12:46:18 24 A. Not that I remember.

12:46:18 25 (Delgado Deposition Exhibit 18

Reynolds M. Delgado III, M.D.

Page 82

12:46:18 1 marked.)

12:46:18 2 BY MR. MORIARTY:

12:46:18 3 Q. Okay. All right. This is Exhibit 18,  
12:46:25 4 I've had marked. This is a statement from the FDA,  
12:46:33 5 July 8th, 2009. Have you ever seen this before,  
12:46:36 6 regarding recalls?

12:46:39 7 A. No.

12:46:40 8 Q. Specifically, here is a section from the  
12:46:45 9 FDA about the Digitek recall, and it says, "Actavis  
12:46:54 10 detected a very small number of oversized tablets in  
12:46:57 11 this lot (specifically, 20 double-size tablets in a  
12:47:01 12 sample of approximately 4.8 million tablets).

12:47:05 13 "Although Actavis attempted to  
12:47:07 14 remove the affected Digitek tablets through visual  
12:47:10 15 inspection, FDA determined that this method of  
12:47:14 16 removal was inadequate to assure the product's  
12:47:16 17 quality and consistency in accordance with the  
12:47:19 18 current good manufacturing practice regulations."

12:47:21 19 Do you see that?

12:47:21 20 A. Yes.

12:47:21 21 Q. "Since the detection of the  
12:47:24 22 manufacturing problem, FDA has been actively engaged  
12:47:27 23 with the company to assure that all potentially  
12:47:30 24 affected lots of Digitek tablets have been  
12:47:34 25 recalled."

Reynolds M. Delgado III, M.D.

Page 83

12:47:35 1 Do you see that?

12:47:35 2 A. Yes.

12:47:35 3 Q. Does any of this ring a bell as if  
12:47:38 4 you've seen this statement before?

12:47:40 5 A. Excuse me. Can I see the whole  
12:47:42 6 document?

12:47:42 7 Q. Sure.

12:47:50 8 A. This, you say, is from the FDA?

12:47:52 9 Q. It is. It's posted on their website.

12:47:57 10 A. At HealthNewsDigest.com? This, I  
12:48:07 11 don't -- I haven't seen this before, but I don't  
12:48:10 12 believe it's from the FDA.

12:48:12 13 Q. Okay. Let me just finish with this.

12:48:15 14 A. They don't talk about innuendo.  
12:48:18 15 Certainly, they don't talk about their own TCPs.

12:48:22 16 Q. And it says here, "In our best judgment,  
12:48:25 17 given the very small number of defective tablets  
12:48:27 18 that may have reached the market and the lack of  
12:48:30 19 reported adverse events before the recall, harm to  
12:48:34 20 patients was very unlikely."

12:48:36 21 Have you ever seen this statement  
12:48:39 22 from the FDA?

12:48:40 23 A. No.

12:48:43 24 MS. RUSNAK: Do you have an extra  
12:48:45 25 copy of that?

Reynolds M. Delgado III, M.D.

Page 84

12:48:46 1 MR. MORIARTY: I don't. They're all  
12:48:48 2 here, and you can copy them at any break.

12:48:50 3 MS. RUSNAK: Not a problem.

12:48:54 4 BY MR. MORIARTY:

12:48:54 5 Q. Now, I have, at the break, opened your  
12:48:59 6 copy of that bound office record to some more of  
12:49:04 7 those medication administration records. Do you see  
12:49:08 8 that?

12:49:08 9 A. Yes.

12:49:09 10 Q. Okay. So at page MVDCA:36, from July of  
12:49:17 11 2007, the digoxin on that particular page is listed  
12:49:23 12 as Lanoxin. Do you see that?

12:49:29 13 A. Yes.

12:49:29 14 Q. And would you assume, as you did  
12:49:33 15 earlier, when I was asking you about those other  
12:49:35 16 exhibits, that the hospital has some way of tracking  
12:49:40 17 what, in fact, is being dispensed from the pharmacy  
12:49:44 18 at that time?

12:49:46 19 A. Yes.

12:49:48 20 Q. And on the next page, MVDCA:10, there's  
12:49:59 21 another one that says "digoxin (Lanoxin)." Do you  
12:50:06 22 see that?

12:50:06 23 A. Yes.

12:50:06 24 Q. From August of 2007. You see that?

12:50:10 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 85

12:50:15 1 Q. And then it goes on; and the next page  
12:50:20 2 of your chart, same sort of format, MVDCA:16,  
12:50:24 3 another one where it says "digoxin (Lanoxin)," with  
12:50:31 4 a date in September of 2007, correct?

12:50:38 5 A. Yes.

12:50:46 6 Q. All right. And there are more of these  
12:50:48 7 in your chart. I don't need to go over them.  
12:50:52 8 Again, you'd assume that they are trying to properly  
12:50:56 9 track the actual product they dispense from the  
12:50:59 10 pharmacy, correct?

12:51:00 11 A. Yes.

12:51:00 12 Q. Are you on any sort of committee that  
12:51:05 13 has input into what pharmaceutical products are  
12:51:09 14 ordered or not ordered by the St. Luke's Hospital  
12:51:13 15 pharmacy?

12:51:13 16 A. No.

12:51:14 17 Q. Okay. Let's go back. I put a paperclip  
12:51:19 18 on the top of a page earlier in the chart. It's an  
12:51:25 19 office visit to your office of December 9th, 2004.  
12:51:31 20 Do you see that?

12:51:31 21 A. Yes.

12:51:31 22 Q. Page MVDCA:108.

12:51:39 23 Was she still on digoxin, .125?

12:51:57 24 It's on the left under "Current Medications," top  
12:52:02 25 third of the page.

Reynolds M. Delgado III, M.D.

Page 86

12:52:02 1 A. Yes.

12:52:03 2 Q. All right. And can you read to me the  
12:52:07 3 problem list at the far right under "History/Problem  
12:52:12 4 List"?

12:52:14 5 A. "CHF," number 1, with some words after  
12:52:23 6 that I can't read. Number 2, "Obesity." Number 3,  
12:52:30 7 "Insomnia." Number 4, "Concern for metabolic  
12:52:34 8 syndrome." Number 5, "Asymmetric swelling of lower  
12:52:42 9 extremity." Number 6, "Noncompliance."

12:52:45 10 Q. All right. What was the noncompliance?

12:52:48 11 A. I don't know.

12:52:53 12 Q. What was the metabolic syndrome or  
12:52:56 13 concern for metabolic syndrome?

12:53:00 14 A. Metabolic syndrome is a very complex --  
12:53:07 15 would be an understatement -- syndrome that  
12:53:13 16 basically, in lay terms, relates to prediabetes and  
12:53:19 17 increased risk for cardiovascular events.

12:53:24 18 Q. Okay. Is that because of her  
12:53:25 19 longstanding obesity?

12:53:26 20 A. That's a part of it.

12:53:28 21 Q. What are the other components of it?

12:53:30 22 A. Don't ask me to recite it all. It's all  
12:53:34 23 very complicated.

12:53:35 24 Q. Give me a general thumbnail, the  
12:53:37 25 Reader's Digest version of that.

Reynolds M. Delgado III, M.D.

Page 87

12:53:39 1 A. Glucose intolerance; certain BMI, body  
12:53:44 2 mass index; lipid abnormalities; hypertension;  
12:53:51 3 things like that.

12:53:51 4 Q. Okay. Now, on the booklet version of  
12:53:55 5 this that you have in front of you, look at the  
12:53:57 6 bottom where it says "Plan." Do you see that?

12:54:02 7 A. Yes.

12:54:04 8 Q. Much of it is unreadable; would you  
12:54:06 9 agree with me?

12:54:07 10 A. I can read it. In the plan?

12:54:14 11 Q. You can?

12:54:15 12 A. Yes.

12:54:15 13 Q. Whew. Okay. Using either that page or  
12:54:19 14 the one from your actual office record, in front of  
12:54:23 15 you on the table, tell me what items 2 through 6  
12:54:29 16 are.

12:54:29 17 A. Oh, I'm sorry. The plan I was looking  
12:54:32 18 at is up here, not down there.

12:54:33 19 Q. Way at the bottom.

12:54:35 20 A. You're talking about the one way at the  
12:54:36 21 bottom. That one must have copied wrong, because  
12:54:40 22 it's not readable.

12:54:41 23 Q. Can you find that page in the actual  
12:54:43 24 chart you have with you? December 9, 2004.

12:54:55 25 A. 12/9/4.



Reynolds M. Delgado III, M.D.

Page 88

12:55:04 1 (Witness reviews document.)

12:56:37 2 A. Yes, I have it.

12:56:38 3 BY MR. MORIARTY:

12:56:39 4 Q. Okay. Could you just read all the

12:56:40 5 numbers in the plan at the bottom of the page?

12:56:42 6 A. No. They're --

12:56:44 7 Q. They're unreadable too?

12:56:45 8 A. -- unreadable as well.

12:56:47 9 Q. Is that the original that you have with

12:56:49 10 you?

12:56:49 11 A. No.

12:56:49 12 Q. Where is the original?

12:56:50 13 A. At CHF clinic.

12:56:53 14 Q. All right. Is the CHF clinic different

12:56:58 15 from Delgado Cardiovascular?

12:57:01 16 A. Yes.

12:57:01 17 Q. Where is the CHF clinic?

12:57:05 18 A. It's located within the hospital,

12:57:07 19 St. Luke's Hospital.

12:57:07 20 Q. All right. So you see patients there?

12:57:08 21 A. Yes.

12:57:09 22 Q. All right. Up through December of 2004,

12:57:14 23 had you ever recorded a diagnosis of digoxin

12:57:22 24 toxicity for Mimi Rivera-Vega?

12:57:23 25 A. Not that I remember.

Reynolds M. Delgado III, M.D.

Page 89

12:57:27 1 Q. Up until December of 2004, had she ever  
12:57:30 2 had any instances of elevated serum digoxin levels?

12:57:33 3 A. Not that I remember.

12:57:35 4 Q. So if you flip a couple pages further in  
12:57:47 5 your chart to January 6th, 2005 -- and I don't care  
12:57:56 6 which version of the chart you use over there.

12:58:14 7 January 6th, '05, should have been the next note  
12:58:18 8 after the one we just talked about, and I think it's  
12:58:20 9 at the CHF clinic.

12:58:22 10 A. I have 1/15/04.

12:58:27 11 Q. No, the other direction. We were just  
12:58:29 12 in December of '04. I want to go to January of '05.

12:58:38 13 A. 1/6/05. Yes.

12:58:40 14 Q. Okay. At the bottom, do you see that  
12:58:42 15 much of the plan is unreadable?

12:58:44 16 A. Yes.

12:58:45 17 Q. And it is on your copy there as well?

12:58:46 18 A. Yes.

12:58:46 19 Q. This is another page, the original of  
12:58:48 20 which is at the heart-failure clinic?

12:58:51 21 A. Yes.

12:58:51 22 Q. Okay. Up under the "Subjective"  
12:59:00 23 section, do you see where it says, "Snores. Shallow  
12:59:04 24 breathing. Husband reports periods of no," double  
12:59:08 25 underlined, "breathing"?

Reynolds M. Delgado III, M.D.

Page 90

12:59:10 1 A. Yes.

12:59:10 2 Q. At some point, did you initiate a workup

12:59:14 3 for obstructive sleep apnea?

12:59:17 4 A. Yes.

12:59:17 5 Q. And she was diagnosed with that

12:59:20 6 condition?

12:59:20 7 A. Yes.

12:59:21 8 Q. And prescribed a CPAP machine?

12:59:25 9 A. Right.

12:59:25 10 Q. Was she compliant with her CPAP machine?

12:59:29 11 A. As far as I know.

12:59:33 12 Q. Do you know if there are notes in your

12:59:34 13 chart that say otherwise?

12:59:36 14 A. I don't.

12:59:41 15 Q. And in the next section down under

12:59:45 16 "Objective," it looks to me like it says, "Reports

12:59:49 17 being unable to do anything she wants."

12:59:52 18 Do you see that?

12:59:53 19 A. I'm sorry, I lost the page.

12:59:54 20 Q. That's okay. January 6th, 2005. It's

13:00:00 21 MVDCA:103. No, you're going the wrong way.

13:00:06 22 A. Ah.

13:00:07 23 Q. I keep my black booklet in chronological

13:00:11 24 order, not reverse.

13:00:14 25 A. Okay.

Reynolds M. Delgado III, M.D.

Page 91

13:00:15 1 Q. You got it?

13:00:16 2 A. Yes.

13:00:16 3 Q. Okay. So under the "Objective" section,  
13:00:18 4 do you see where it says, "Reports being unable to  
13:00:21 5 do anything she wants"?

13:00:22 6 A. Yes.

13:00:23 7 Q. And, I mean, is this because of her poor  
13:00:27 8 cardiac function?

13:00:40 9 A. I'm sorry. I think that says, "Reports  
13:00:42 10 being able to do anything she wants."

13:00:44 11 Q. Oh. Okay. All right. That's fine.

13:00:57 12 Go forward in the black book to  
13:01:01 13 August of 2006, so it's going to be 10 or 15 pages  
13:01:10 14 down the road. 8/10/06. It's MVDCA:59.

13:01:24 15 A. Yes.

13:01:24 16 Q. Way at the bottom under "Plan," item 2,  
13:01:29 17 "Heart-failure education, August 16th, 11:30 to  
13:01:33 18 1:00 o'clock." Do you see that?

13:01:35 19 A. Yes.

13:01:35 20 Q. What is that a reference to?

13:01:37 21 A. That's an appointment for her to come to  
13:01:42 22 a heart-failure education class.

13:01:44 23 Q. Who teaches it?

13:01:45 24 A. The nurse practitioners at the  
13:01:50 25 heart-failure clinic.

Reynolds M. Delgado III, M.D.

Page 92

13:01:51 1 Q. What do they teach?

13:01:53 2 A. They primarily teach the patients about  
13:01:56 3 the illness and the proper diet; proper lifestyle  
13:02:08 4 modification; about their medicines, about how they  
13:02:15 5 work, et cetera.

13:02:18 6 Q. Possible adverse consequences of the  
13:02:23 7 medicines?

13:02:24 8 A. Yes.

13:02:25 9 Q. And I assume one of those medicines  
13:02:28 10 would be digoxin?

13:02:30 11 A. Yes.

13:02:31 12 Q. Does the heart-failure education program  
13:02:41 13 have written handouts?

13:02:42 14 A. I don't know if we do now, or even then,  
13:02:53 15 actually. No, I don't know.

13:02:54 16 Q. What about videos?

13:02:56 17 A. Yes.

13:02:57 18 Q. Okay. At some point, did Mimi get a  
13:03:08 19 Medtronic implantable defibrillator?

13:03:12 20 A. I don't know if -- I don't know which  
13:03:23 21 type. I know she had a defibrillator. It says here  
13:03:27 22 "ASD shock," so -- and I remember she had a  
13:03:31 23 defibrillator, yes.

13:03:32 24 Q. Do you know anything about whether her  
13:03:35 25 defibrillator was recalled?

Reynolds M. Delgado III, M.D.

Page 93

13:03:36 1 A. Not that I know of.

13:03:38 2 Q. Do you know anything about whether her  
13:03:39 3 defibrillator was ever explanted because of a  
13:03:43 4 recall?

13:03:43 5 A. No.

13:03:43 6 Q. I want you to assume that Scottie, her  
13:03:52 7 husband, testified that she had a Medtronic device  
13:03:55 8 that was recalled; and I asked him if it was  
13:04:00 9 explanted, and he said he didn't think so.

13:04:03 10 If a recalled line of defibrillators  
13:04:08 11 was in place but not causing any problems, would it  
13:04:12 12 typically be left in place?

13:04:17 13 A. That's not an answerable question,  
13:04:22 14 because each situation has to be individualized.

13:04:25 15 Q. Okay.

13:04:25 16 A. There are FDA advisories as to the  
13:04:29 17 specific circumstances.

13:04:31 18 Q. All right.

13:04:32 19 A. With the specific leads and device,  
13:04:35 20 blah, blah, blah.

13:04:36 21 Q. Would there be some separate file for  
13:04:38 22 Mimi regarding any FDA correspondence about her type  
13:04:45 23 of device?

13:04:45 24 A. Not that I know of.

13:04:47 25 Q. All right. Let's go to October 30,

Reynolds M. Delgado III, M.D.

Page 94

13:05:05 1 2007, probably three or four pages ahead of where  
13:05:07 2 you are in the black binder. It's MVDCA:53. It's a  
13:05:26 3 home healthcare order.

13:05:41 4 A. Yes.

13:05:41 5 Q. So what was she being prescribed for  
13:05:47 6 home healthcare? Looks like "IV milrinone" to me.

13:06:00 7 A. Yes.

13:06:00 8 Q. Is there anything else?

13:06:01 9 A. Dextrose solution.

13:06:02 10 Q. Okay. That's just what they add the  
13:06:04 11 milrinone to for infusion purposes?

13:06:08 12 A. Yes.

13:06:08 13 Q. So what was the purpose of you  
13:06:10 14 prescribing home IV milrinone for her in the fall of  
13:06:15 15 2007?

13:06:15 16 A. I don't remember the specific  
13:06:25 17 circumstances, where I started that. But the  
13:06:33 18 general reason why I would do that would be, again,  
13:06:37 19 bridge-to-transplant or palliative care.

13:06:38 20 Q. When you say "palliative care," what do  
13:06:40 21 you mean?

13:06:41 22 A. To make people have less symptoms of an  
13:06:48 23 illness at end-of-life.

13:06:52 24 Q. Okay. So, in other words, if I hear  
13:06:57 25 what you're saying, you were getting to some pretty

Reynolds M. Delgado III, M.D.

Page 95

13:07:02 1 critical decision times for Mimi Rivera-Vega; is  
13:07:07 2 that true?

13:07:09 3 MS. RUSNAK: Objection, form.

13:07:10 4 A. No, she wasn't a palliative-care case.  
13:07:13 5 She was a bridge-to-transplant case.

13:07:13 6 BY MR. MORIARTY:

13:07:13 7 Q. Okay.

13:07:16 8 A. That much, I remember.

13:07:17 9 Q. Well, I mean, that's a decision that has  
13:07:18 10 to be made, whether she's a palliative case or a  
13:07:22 11 bridge-to-transplant case, right?

13:07:25 12 A. Yes.

13:07:25 13 Q. I mean, that's a pretty important  
13:07:28 14 decision, correct?

13:07:28 15 A. Yes.

13:07:29 16 Q. All right. In heart-failure patients,  
13:07:37 17 the effect of digoxin or the use of digoxin is for  
13:07:42 18 its inotropic activity; isn't that correct?

13:07:44 19 A. Yes.

13:07:45 20 Q. So when you are prescribing home  
13:07:49 21 intravenous milrinone, would it be fair for me to  
13:07:56 22 say that that is an extremely potent type of  
13:08:01 23 inotropic therapy?

13:08:08 24 A. No.

13:08:09 25 Q. Is it substantially more potent than



Reynolds M. Delgado III, M.D.

Page 96

13:08:11 1 digoxin tablets, regardless of whether it's .125

13:08:16 2 or .250?

13:08:18 3 A. It would depend on the dose of both meds  
13:08:22 4 and the way it's administered. This is milrinone by  
13:08:25 5 continuous infusion.

13:08:26 6 Q. I'm sorry?

13:08:26 7 A. She was given milrinone by continuous  
13:08:28 8 infusion. You can't compare it to the dosing of  
13:08:31 9 oral.

13:08:31 10 Q. Okay. So why are you giving her home IV  
13:08:35 11 milrinone as opposed to a lot more digoxin?

13:08:40 12 A. The digoxin in higher doses increases  
13:08:48 13 mortality.

13:08:49 14 Q. Okay. Without increasing efficacy,  
13:08:50 15 right?

13:08:51 16 A. Correct.

13:08:51 17 Q. So in the use of medical therapy for a  
13:09:00 18 patient like this, is it a good idea to have a lot  
13:09:03 19 of options available to you: oral tablets, IV  
13:09:09 20 infusions, things of that nature?

13:09:11 21 A. Yes.

13:09:15 22 Q. All right. And the IV milrinone is a  
13:09:18 23 way to give her more inotropic support without the  
13:09:26 24 risks of high digoxin doses, correct?

13:09:32 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 97

13:09:32 1 Q. And did she need higher levels of  
13:09:37 2 inotropic support for her heart failure than she was  
13:09:41 3 getting with oral digoxin?

13:09:47 4 A. I can't answer that one, either. The  
13:09:54 5 milrinone is given to achieve a specific purpose;  
13:09:56 6 and this purpose is, as we discussed, BTT.

13:10:04 7 Q. But why -- if they have the same  
13:10:12 8 essential mechanism of action, why is IV milrinone  
13:10:19 9 the better bridge-to-transplant therapy?

13:10:24 10 A. It's not necessarily better. They were  
13:10:27 11 used in combination, as I remember.

13:10:29 12 Q. All right. Well, is the only reason  
13:10:32 13 because you can get higher levels of inotropic  
13:10:36 14 support without the risk of digoxin?

13:10:44 15 A. Is that the only reason I'm giving it,  
13:10:47 16 the milrinone?

13:10:48 17 Q. Let me withdraw the question.  
13:10:49 18 Did she need more inotropic support  
13:10:55 19 than the level of digoxin that she was getting at  
13:10:58 20 that point, which was .250 milligrams a day?

13:11:03 21 A. Again, you don't understand the concept  
13:11:09 22 of BTT. You're trying to achieve a goal, so whether  
13:11:14 23 or not she needed it, you have to say what she  
13:11:16 24 needed it for. If you need it to achieve a BTT  
13:11:20 25 goal, then yes. But do you need it to feel better,

Reynolds M. Delgado III, M.D.

Page 98

13:11:24 1 walk farther? No.

13:11:26 2 Q. Okay. Why is the IV milrinone a better  
13:11:29 3 strategy for bridge-to-transplant than just oral  
13:11:38 4 digoxin?

13:11:38 5 A. I don't think I can answer that one,  
13:11:46 6 either. The bridge-to-transplant -- repeat the  
13:11:52 7 question. How did you ask it?

13:11:53 8 Q. Okay. Let's go back here.

13:11:55 9 A. Because this is a very complex thing.  
13:11:57 10 It's something that is very difficult to explain to  
13:12:01 11 lay people. I'm sorry.

13:12:02 12 Q. Okay. That's fine. You can explain it  
13:12:05 13 to me as if I was a cardiologist for all I care.

13:12:10 14 A. Well, that too.

13:12:12 15 Q. Difficult to explain to your colleagues?

13:12:14 16 A. Absolutely.

13:12:15 17 Q. All right. Let's go back over some  
13:12:19 18 history here.

13:12:20 19 A. Uh-huh.

13:12:20 20 Q. Mimi, you decided and your colleagues  
13:12:25 21 decided, ultimately was going to need a heart  
13:12:30 22 transplant, correct?

13:12:31 23 A. Yes.

13:12:31 24 Q. Okay. And do you have any idea when you  
13:12:35 25 started to think that that was a likely course for

Reynolds M. Delgado III, M.D.

Page 99

13:12:37 1 her?

13:12:38 2 A. No.

13:12:38 3 Q. And why was it that she was going to  
13:12:42 4 need a transplant?

13:12:44 5 A. At some point as she got older, because  
13:12:51 6 her ejection fraction did not improve, we knew we  
13:12:57 7 would be facing that.

13:12:58 8 Q. And what is it about age and a change in  
13:13:04 9 the ejection fraction that tells you that?

13:13:05 10 A. Unfortunately, everyone's heart function  
13:13:09 11 diminishes with age.

13:13:11 12 Q. Okay. So even though she's 34 or  
13:13:14 13 whatever age it was at the time, 30, 34, she's  
13:13:18 14 getting to that point where you're thinking about  
13:13:20 15 these things, right?

13:13:21 16 A. Yes.

13:13:22 17 Q. Okay. And we all know there's a  
13:13:24 18 shortage of donor hearts, correct?

13:13:28 19 A. Correct.

13:13:28 20 Q. And one of the things that you have done  
13:13:29 21 in your career, and one of your prime academic  
13:13:34 22 interests, is getting people, in the face of a donor  
13:13:39 23 shortage, from heart failure through  
13:13:44 24 bridge-to-transplant, correct?

13:13:45 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 100

13:13:46 1 Q. You are actively involved in LVADs and  
13:13:51 2 other bridge-to-transplant therapies, correct?

13:13:54 3 A. Yes.

13:13:55 4 Q. Okay. So Mimi had been on digoxin for  
13:14:00 5 some period of time, oral, correct?

13:14:03 6 A. Yes.

13:14:03 7 Q. And at varying times, it was .125 and  
13:14:11 8 occasionally .250, correct?

13:14:14 9 A. Correct.

13:14:15 10 Q. Do you know why you went, at some point,  
13:14:17 11 from .125 up to .250?

13:14:23 12 A. I don't remember.

13:14:23 13 Q. Was it, most likely, symptom control?

13:14:25 14 A. I really don't remember. It may have  
13:14:29 15 not even been me. It may have been the nurse  
13:14:32 16 practitioner in the heart care clinic or one of my  
13:14:35 17 partner docs.

13:14:37 18 Q. Well, certainly if you noticed that it  
13:14:39 19 was .250 in the records, you didn't necessarily  
13:14:41 20 disagree with it, correct?

13:14:42 21 A. Correct.

13:14:42 22 Q. That's a judgment call, right?

13:14:45 23 A. Yes.

13:14:45 24 Q. And if .250 digoxin of whatever brand  
13:14:52 25 was causing her problems, it could have been scaled

Reynolds M. Delgado III, M.D.

Page 101

13:14:59 1 back to the preceding .125, correct?

13:15:05 2 MS. RUSNAK: Objection, form.

13:15:06 3 A. I don't understand that question,  
13:15:07 4 either.

13:15:08 5 BY MR. MORIARTY:

13:15:08 6 Q. Well, if you increase a patient  
13:15:10 7 from .125 digoxin to .250 digoxin and they begin to  
13:15:14 8 exhibit signs or symptoms of toxicity, you could  
13:15:17 9 scale back the dose, correct?

13:15:19 10 A. Yes.

13:15:19 11 Q. All right. And up until the fall of  
13:15:25 12 2007, when you're writing these home healthcare  
13:15:29 13 orders, to the best of your knowledge, had you ever  
13:15:33 14 made a notation in her medical record that she had  
13:15:37 15 digoxin toxicity?

13:15:37 16 A. Not that I know of.

13:15:38 17 Q. And up until October of 2007, other than  
13:15:49 18 one elevated level as an inpatient at St. Luke's,  
13:15:53 19 had you ever seen an elevated serum digoxin  
13:15:56 20 concentration?

13:15:57 21 A. I'm sorry, repeat that date again.

13:16:00 22 Q. There was an elevated serum digoxin --  
13:16:03 23 I'm sorry --

13:16:04 24 A. Not the question, the date. I mean, up  
13:16:06 25 to?

Reynolds M. Delgado III, M.D.

Page 102

13:16:06 1 Q. Up to this time, in October of 2007,  
13:16:09 2 when you're writing this home healthcare order --

13:16:11 3 A. Right.

13:16:12 4 Q. -- had you ever seen more than one  
13:16:14 5 elevated serum digoxin concentration in all of her  
13:16:17 6 medical records?

13:16:24 7 A. No.

13:16:24 8 Q. Do you remember the one elevated level  
13:16:28 9 from a hospitalization in August of 2007?

13:16:32 10 A. Yes.

13:16:32 11 Q. Do you know what brand of digoxin she  
13:16:34 12 was being administered at the time?

13:16:35 13 A. No.

13:16:36 14 Q. Do you know -- did you ever come to an  
13:16:39 15 opinion as to what the cause of that elevated level  
13:16:41 16 was?

13:16:41 17 A. I have a suspicion that it was caused by  
13:16:51 18 her having just recently had a cholecystectomy.

13:16:58 19 Q. And what would the connection be between  
13:17:00 20 the recent string of admissions to the hospital for  
13:17:05 21 abdominal problems to the elevated level?

13:17:10 22 A. That's not what I said. I said the  
13:17:17 23 cholecystectomy.

13:17:18 24 Q. Okay. What would the relationship  
13:17:19 25 between the cholecystectomy and the elevated level

Reynolds M. Delgado III, M.D.

Page 103

13:17:22 1 be?

13:17:22 2 A. Cholecystectomy is abdominal surgery,  
13:17:26 3 and so it requires an opening of the abdomen and  
13:17:31 4 removing the gallbladder. And so, commonly, you  
13:17:35 5 know, almost universally for a period of time after  
13:17:37 6 that, there's a period of anorexia and ileus.

13:17:42 7 During those times, patients will  
13:17:43 8 always have perturbations of blood levels or  
13:17:48 9 whatever and often will have volume depletion most  
13:17:52 10 commonly, and so that's typical.

13:17:57 11 Q. Okay. I was talking about this overall  
13:18:04 12 history regarding Mimi. And at some point, did you  
13:18:10 13 and Mimi, in consultation with other specialists,  
13:18:16 14 decide that it was in her best interest to have a  
13:18:20 15 bariatric surgical procedure to help in getting her  
13:18:26 16 eligible for the transplant list?

13:18:28 17 A. Yes.

13:18:29 18 Q. All right. So where we got off the main  
13:18:36 19 track and went on the side road was you giving me  
13:18:42 20 the best explanation you can for why IV milrinone at  
13:18:49 21 home is the bridge-to-transplant treatment of  
13:18:57 22 choice, as opposed to just oral digoxin.

13:19:03 23 MS. RUSNAK: Objection, form.

13:19:09 24 A. I didn't get that.

13:19:11 25 BY MR. MORIARTY:



Reynolds M. Delgado III, M.D.

Page 104

13:19:11 1 Q. Okay.

13:19:11 2 A. I'm not sure that -- I don't understand.

13:19:15 3 Sorry.

13:19:15 4 Q. All right. Well, we've established that  
13:19:18 5 there's this decision that's going on for,  
13:19:21 6 potentially, a couple of years, that she's going to  
13:19:25 7 ultimately need a heart transplant, right?

13:19:28 8 A. It would be better called a prediction,  
13:19:39 9 not a decision.

13:19:40 10 Q. Okay. A prediction, right?

13:19:44 11 A. Yes.

13:19:44 12 Q. And you've got various strategies  
13:19:51 13 available to you for the management of her  
13:19:54 14 heart-failure symptoms, correct?

13:19:55 15 A. Yes.

13:19:55 16 Q. And in October of 2007, you have several  
13:20:03 17 therapeutic choices available to you, correct?

13:20:06 18 A. Yes.

13:20:06 19 Q. One is to just continue her on her  
13:20:10 20 existing therapies, which appear to be things like  
13:20:33 21 the ACE inhibitor and the digoxin and the diuretic,  
13:20:39 22 correct? That's one option?

13:20:42 23 A. Yes.

13:20:42 24 Q. And another option is to add IV  
13:20:48 25 milrinone into the mix here, right?

Reynolds M. Delgado III, M.D.

Page 105

13:20:50 1 A. Yes.

13:20:51 2 Q. Okay. Tell me, as succinctly as you  
13:20:54 3 can, why the IV milrinone is added, other than that  
13:21:02 4 it's a better bridge-to-transplant strategy.

13:21:05 5 A. Well, that is the reason.

13:21:10 6 Q. Okay.

13:21:10 7 A. It's a bridge-to-transplant strategy.

13:21:14 8 Q. All right. Is there a publication,  
13:21:17 9 anything you've written or anything you're aware of,  
13:21:19 10 that would give me a more in-depth analysis of why  
13:21:25 11 the IV milrinone is the better strategy?

13:21:29 12 A. Hmm. Not that I can think of, but you  
13:21:41 13 may want to reference the UNOS criteria for organ  
13:21:52 14 status procurement.

13:21:53 15 Q. Okay. Do those require that there have  
13:21:57 16 been other therapeutic measures taken in order to  
13:22:02 17 ultimately qualify?

13:22:07 18 A. No.

13:22:07 19 Q. Some electrocardiograph machines, when  
13:22:18 20 they detect a pattern consistent with digoxin  
13:22:24 21 toxicity, will print out something to that effect in  
13:22:28 22 the printout. Have you ever seen that?

13:22:30 23 A. Yes.

13:22:30 24 Q. Do you know whether the EKG machines at  
13:22:35 25 your offices or at St. Luke's have that capability?

Reynolds M. Delgado III, M.D.

Page 106

13:22:37 1 A. Definitely not in my office. I don't  
13:22:46 2 allow it in my office. At the hospital, the  
13:22:49 3 machines do have that capability. They're overread,  
13:22:52 4 though, by cardiologists.

13:22:53 5 Q. Why don't you allow that at your office?

13:22:55 6 A. There's an old saying that says bad data  
13:23:01 7 is worse than no data.

13:23:05 8 Q. And how does that maxim apply to the  
13:23:10 9 question I asked you?

13:23:11 10 A. I believe it's bad data.

13:23:13 11 Q. Okay. Why is it bad data?

13:23:15 12 A. It's computer-generated.

13:23:17 13 Q. All right. Okay. Look in your record,  
13:23:40 14 please, the black-binder version, under the brown  
13:23:45 15 tab for "Consults," and go back to the fourth page.  
13:23:54 16 It's a letter to you from Houston Infectious Disease  
13:23:58 17 Associated. Do you see that?

13:23:59 18 A. Yes.

13:24:00 19 Q. I don't know how the Bates-labeling on  
13:24:05 20 this changed, but it says "Mimi Vega 00074." Do you  
13:24:14 21 see that?

13:24:14 22 A. Yes.

13:24:15 23 Q. And Dr. Zeluff -- is that how you  
13:24:18 24 pronounce his name?

13:24:18 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 107

13:24:19 1 Q. -- in the second sentence, refers to her  
13:24:20 2 having end-stage postpartum cardiomyopathy. Do you  
13:24:24 3 see that?

13:24:24 4 A. Yes.

13:24:25 5 Q. Do you agree with his statement?

13:24:27 6 A. No.

13:24:30 7 Q. Did you agree with it at the time?

13:24:34 8 A. I don't know. I don't remember.

13:24:37 9 Q. All right. Is that a phrase you use in  
13:24:41 10 your own practice?

13:24:42 11 A. No.

13:24:42 12 Q. Now, if Mimi Rivera-Vega went to the  
13:25:23 13 hospital with shortness of breath, diminished  
13:25:31 14 ability to function, things of that nature, are  
13:25:35 15 those, in general, the kind of problems that you  
13:25:38 16 expect with acute exacerbations of heart failure?

13:25:45 17 A. Yes.

13:25:45 18 Q. In general, did she experience a string  
13:25:51 19 of such admissions from the late summer through the  
13:25:58 20 end of calendar year 2007?

13:26:02 21 A. Are you trying to make the leap to say  
13:26:11 22 that they were all because of heart failure? The  
13:26:14 23 answer is no.

13:26:15 24 Q. Okay. Why did she have these admissions  
13:26:19 25 in the late summer and throughout the fall of 2007,

Reynolds M. Delgado III, M.D.

Page 108

13:26:23 1 in general, if you remember?

13:26:24 2 A. There were multiple precipitators for  
13:26:28 3 her coming in the hospital. Some were related to  
13:26:30 4 that cholecystectomy; some were related to  
13:26:36 5 upper-respiratory infections; some were related to,  
13:26:41 6 I think, the hysterectomy, or came around that time  
13:26:45 7 period.

13:26:48 8 Q. In a patient like Mimi Rivera-Vega, are  
13:26:56 9 these sort of abdominal procedures the kind of  
13:26:59 10 things that could precipitate electrolyte  
13:27:05 11 imbalances?

13:27:06 12 A. Yes.

13:27:06 13 Q. Can they precipitate exacerbations of  
13:27:11 14 heart-failure symptoms?

13:27:13 15 A. Yes.

13:27:14 16 Q. In any of the hospital charts for the  
13:27:20 17 admissions in the late summer and the fall of 2007,  
13:27:25 18 do you ever recall recording a diagnosis of digoxin  
13:27:30 19 toxicity?

13:27:32 20 A. No.

13:27:32 21 Q. Can you go back to the end of the purple  
13:27:53 22 section of that black binder, the chart that I have  
13:27:56 23 in front of you. There are these charts in your  
13:27:59 24 office; they look like this (indicating).

13:28:03 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 109

13:28:03 1 Q. You see that?

13:28:06 2 And the first one that I found is

13:28:08 3 dated -- I'm sorry, Bates-stamped MVDCA:24. Can you  
13:28:16 4 just find that one?

13:28:24 5 A. Yes.

13:28:24 6 Q. Is this a form that you and your staff  
13:28:29 7 developed?

13:28:30 8 A. Yes.

13:28:30 9 Q. Explain it to me, if you can.

13:28:35 10 A. The St. Luke's Hospital EMR has the  
13:28:40 11 ability to create graphic reports.

13:28:47 12 Q. That's "electronic medical record"?

13:28:49 13 A. Yes.

13:28:49 14 Q. Okay. Go ahead.

13:28:50 15 A. And these are graphic reports of digoxin  
13:28:56 16 levels over a time period.

13:28:58 17 Q. Okay. So the top one of the graphs,  
13:29:03 18 where it says "Component Value," what is that  
13:29:06 19 reflecting or recording?

13:29:08 20 A. I really don't know. I looked at that  
13:29:12 21 the other night. I couldn't figure it out.

13:29:15 22 Q. I mean, it doesn't appear to correlate  
13:29:17 23 with dates in the boxes at the top, does it?

13:29:20 24 A. I really don't know because -- well, I  
13:29:31 25 don't know what "component value" means there,

Reynolds M. Delgado III, M.D.

Page 110

13:29:32 1 because it's in the millions.

13:29:34 2 Q. Okay. So to what use do you put these  
13:29:44 3 charts in your clinical practice?

13:29:47 4 A. The -- for this purpose, looking at  
13:30:02 5 digoxin levels over a period of the, the best way, I  
13:30:04 6 think, to do it is just to have the levels and the  
13:30:07 7 dates.

13:30:07 8 Q. Okay. Which are at the top, right?

13:30:09 9 A. Correct.

13:30:10 10 Q. And it has collection dates, and it  
13:30:11 11 actually has the time of last dose, also, right?

13:30:14 12 A. Yes.

13:30:14 13 Q. So you can compare whether it's drawn  
13:30:17 14 within that appropriate window?

13:30:18 15 A. Yes.

13:30:19 16 Q. And the only one of these levels that is  
13:30:23 17 outside the lab's therapeutic range on the high side  
13:30:29 18 is the one August 3rd, 2007, correct?

13:30:32 19 A. Yes.

13:30:32 20 Q. And that's the post-cholecystectomy  
13:30:36 21 level that we talked about before?

13:30:37 22 A. Yes.

13:30:37 23 Q. Would any of the levels that are  
13:30:43 24 recorded on these pages, MVDCA:24, 25, 26 and 27 or  
13:30:53 25 28, lead you to conclude, by themselves, that she

Reynolds M. Delgado III, M.D.

Page 111

13:31:00 1 had digoxin toxicity?

13:31:07 2 A. I don't think I can answer that one.

13:31:17 3 You're making a mistake in equating digoxin toxicity  
13:31:23 4 to increased mortality due to digoxin.

13:31:27 5 Q. I didn't say anything about mortality.

13:31:29 6 I'm just asking if these levels, in and of

13:31:35 7 themselves, would indicate that she had digoxin

13:31:38 8 toxicity, as is in these recordings?

13:31:44 9 A. That's exactly the point. You don't

13:31:46 10 care about the digoxin level. All you care about is

13:31:48 11 mortality. All you care about is what the effect is

13:31:53 12 on the patient. So --

13:31:54 13 Q. What do you mean by that?

13:31:55 14 A. -- I can't answer your question. That's

13:31:57 15 what I'm getting to.

13:31:59 16 Q. In what sense do you only care about

13:32:02 17 mortality, in this context?

13:32:05 18 A. Well, if -- since she was my patient,

13:32:07 19 I'll use her as a good example. This young woman, I

13:32:11 20 had a responsibility to her life and to her

13:32:18 21 well-being. That, to me, would be more important

13:32:21 22 than a blood level of something; you know, a lab

13:32:27 23 report.

13:32:27 24 Q. Sure.

13:32:28 25 And we talked about this hours ago,



Reynolds M. Delgado III, M.D.

Page 112

13:32:30 1 when you told me you don't just treat a level,  
13:32:33 2 because it's just a lab report, right?

13:32:35 3 A. Yes.

13:32:36 4 Q. Okay. Well, let's put it another way.

13:32:48 5 In following her and ordering these levels, what was  
13:32:54 6 their significance to you? There's July of '07,  
13:33:01 7 August of '07, on through sometime in early 2008;  
13:33:07 8 were these levels of significance to you in any  
13:33:11 9 aspect of your therapeutic management of her?

13:33:13 10 A. Which of those questions should I  
13:33:15 11 answer? Because it's -- that's relevant.

13:33:20 12 MR. WILLIAMSON: I'm sure he'll  
13:33:22 13 rephrase to ask you one specific question.

13:33:29 14 BY MR. MORIARTY:

13:33:30 15 Q. Did any of these levels cause you to  
13:33:32 16 change a management approach?

13:33:41 17 A. Hmm. I don't remember.

13:33:52 18 Q. Well, of what significance were these  
13:33:55 19 levels to you?

13:33:58 20 A. In retrospect, they were.

13:34:01 21 Q. Well, at the time?

13:34:03 22 A. I don't remember.

13:34:05 23 Q. In retrospect, what's their  
13:34:08 24 significance?

13:34:08 25 A. The two levels that were elevated

Reynolds M. Delgado III, M.D.

Page 113

13:34:11 1 above .9 are of significance, in retrospect.

13:34:22 2 Q. Okay. So let's deal with --

13:34:25 3 A. I don't remember what I did about them  
13:34:26 4 at the time.

13:34:26 5 Q. Let's deal with the August 3rd, 2007.

13:34:33 6 3.2, what is the significance of that to you in  
13:34:37 7 retrospect?

13:34:37 8 A. Nothing.

13:34:38 9 Q. Okay. And the only other level that I  
13:34:43 10 see above .9 -- oh, I'm sorry.

13:34:50 11 Then I see a January 23rd, 2008,  
13:34:53 12 level of 1.2. What was the significance of that to  
13:34:58 13 you at the time?

13:34:59 14 A. I don't remember.

13:35:00 15 Q. What's the significance of it to you in  
13:35:03 16 retrospect?

13:35:04 17 A. That's the signal. Right there's the  
13:35:07 18 signal.

13:35:08 19 Q. The signal of what?

13:35:09 20 A. And then it's backed up by the follow-up  
13:35:12 21 level in February.

13:35:14 22 Q. Signal of what?

13:35:15 23 A. That digoxin killed her.

13:35:21 24 Q. So the level on January 23rd, 2008, was  
13:35:36 25 1.2, and the level on February 28th was 1.2,

Reynolds M. Delgado III, M.D.

Page 114

13:35:41 1 correct?

13:35:41 2 A. Yes.

13:35:41 3 Q. Neither of which is abnormal, according  
13:35:44 4 to the therapeutic levels of the St. Luke's Hospital  
13:35:48 5 lab, correct?

13:35:49 6 A. Yes.

13:35:49 7 Q. And this is a woman who, before that  
13:35:53 8 time, was on bridge-to-transplant therapy, correct?

13:35:57 9 A. Hmm. No.

13:36:05 10 Q. You already told me you gave her IV home  
13:36:08 11 milrinone as bridge-to-transplant therapy.

13:36:10 12 A. No, I didn't.

13:36:11 13 Q. Okay.

13:36:12 14 A. That's a strategy.

13:36:13 15 MR. WILLIAMSON: Wait, wait, wait.

13:36:15 16 A. I'm sorry, I'm confusing you. I'm  
13:36:18 17 clearly confusing you. I'm sorry.

13:36:20 18 MR. WILLIAMSON: No, no. He asked a  
13:36:21 19 question, which you already told him was not a  
13:36:23 20 proper question. You don't want to be arguing. The  
13:36:23 21 court reporter wrote down whatever he asked you.

13:36:25 22 THE WITNESS: Okay.

13:36:25 23 MR. WILLIAMSON: He'll ask you  
13:36:28 24 another question about that, I'm sure.

13:36:34 25 BY MR. MORIARTY:

Reynolds M. Delgado III, M.D.

Page 115

13:36:34 1 Q. So let's just take your statement:

13:36:36 2 What, in retrospect, do these two elevated serum  
13:36:41 3 digoxin concentrations of 1.2 signal to you that  
13:36:46 4 digoxin was some factor in causing her death?

13:36:50 5 A. I'm not sure that's a question.

13:36:59 6 Q. You just told me that these two levels  
13:37:02 7 were a signal that digoxin, retrospectively, caused  
13:37:07 8 her death. What is the scientific basis for that  
13:37:11 9 conclusion?

13:37:17 10 A. It's hard to explain, I guess, but I'll  
13:37:21 11 explain it by just saying that that was the initial  
13:37:25 12 clue, in my mind, that made me understand what led  
13:37:31 13 to her death.

13:37:32 14 Q. Well, you have to explain it to me, to a  
13:37:34 15 reasonable degree of medical probability, what the  
13:37:38 16 connection is here.

13:37:40 17 A. The best way I can do that is for you to  
13:37:44 18 have some understanding of the Kirkwood Adams  
13:37:47 19 article, and whoever, the jury, to have some  
13:37:53 20 understanding of that article.

13:37:55 21 Q. Okay.

13:37:55 22 A. Otherwise, I'm wasting my time, really.

13:37:58 23 Q. I need your explanation.

13:38:00 24 A. My explanation is contained in the Adams  
13:38:03 25 article.

Reynolds M. Delgado III, M.D.

Page 116

13:38:03 1 Q. Okay. Which is that elevated serum  
13:38:07 2 digoxin concentrations can increase mortality,  
13:38:11 3 correct?

13:38:12 4 A. No.

13:38:13 5 Q. What?

13:38:14 6 A. This is why -- I'm sorry I'm confusing  
13:38:18 7 you so much. A report on a lab that comes over a  
13:38:24 8 computer does not do something to someone.

13:38:26 9 Q. Okay.

13:38:26 10 A. The problem that does something to  
13:38:31 11 someone is having an excessive amount of medication  
13:38:36 12 in their system that leads to an outcome, and that's  
13:38:42 13 explained very nicely in the Adams article.

13:38:47 14 Q. Do you have any evidence to indicate  
13:38:51 15 that Mimi Rivera-Vega ever got digoxin that was in  
13:38:57 16 excess of the prescribed dose?

13:39:03 17 A. I believe that's the case, yes.

13:39:14 18 Q. What evidence do you have that Mimi  
13:39:18 19 Rivera, in fact, got digoxin that was in excess of  
13:39:22 20 the prescribed dose?

13:39:22 21 A. The ones I just discussed. The signals  
13:39:24 22 I discussed.

13:39:25 23 Q. Okay. The elevated level of 1.2?

13:39:30 24 A. In conjunction with the fact that she  
13:39:33 25 developed cardiogenic shock and heart failure and

Reynolds M. Delgado III, M.D.

Page 117

13:39:37 1 died.

13:39:38 2 Q. Well, she had heart failure well before  
13:39:41 3 this, correct?

13:39:41 4 A. Not cardiogenic shock and heart failure.  
13:39:46 5 Difference.

13:39:46 6 Q. But she had heart failure before these  
13:39:48 7 dates?

13:39:48 8 A. You don't understand heart failure. You  
13:39:51 9 don't get it. I'm sorry.

13:39:54 10 MR. WILLIAMSON: Tell me when's a  
13:39:55 11 convenient time for a break for lunch. The lunch  
13:40:00 12 has been here for ten minutes. You may need some  
13:40:02 13 follow-up questions right now, or you may want to  
13:40:05 14 take a break right now.

13:40:06 15 MR. MORIARTY: We can break now.  
13:40:07 16 That's fine.

13:40:07 17 MR. WILLIAMSON: Okay.

13:40:08 18 (Recess taken, 1:40 p.m. to  
14:16:50 19 2:16 p.m.)

14:16:52 20 BY MR. MORIARTY:

14:16:56 21 Q. At one time, there was a suspicion that  
14:17:02 22 Mimi Rivera-Vega had uterine cancer, correct?

14:17:04 23 A. Yes.

14:17:05 24 Q. She had a hysterectomy for that reason,  
14:17:09 25 correct?

Reynolds M. Delgado III, M.D.

Page 118

14:17:09 1 A. Yes.

14:17:09 2 Q. Do you know whether she had any  
14:17:12 3 postoperative radiation therapy?

14:17:16 4 A. No. "No," meaning I don't know if she  
14:17:24 5 did.

14:17:24 6 Q. Okay. Do you know if, ultimately, the  
14:17:26 7 surgeons determined that she had cancer?

14:17:29 8 A. No. The pathology report indicated she  
14:17:32 9 did not.

14:17:33 10 Q. What was your goal for the milrinone  
14:17:43 11 therapy?

14:17:45 12 A. It is a preparatory, I guess you could  
14:17:53 13 say, intervention to get her to a transplant at some  
14:18:02 14 point in the future.

14:18:16 15 Q. Exhibit 17, that follow-up on the DIG  
14:18:22 16 trial, was published in February of 2005, correct?

14:18:24 17 A. Yes.

14:18:24 18 Q. Do you think you read it somewhere  
14:18:27 19 within the year following its publication?

14:18:29 20 A. Yes.

14:18:30 21 Q. In the DIG trial, did all people with  
14:18:38 22 heart failure who had serum digoxin concentrations  
14:18:41 23 over 1.2 go into cardiogenic shock?

14:18:46 24 A. No.

14:18:49 25 Q. Did all the people in the DIG trial who

Reynolds M. Delgado III, M.D.

Page 119

14:18:52 1 had serum digoxin concentrations over 1.2 die as a  
14:18:57 2 result of digoxin toxicity?

14:18:59 3 A. No.

14:18:59 4 Q. After the DIG trial was published or  
14:19:03 5 after Exhibit 17 was published, did St. Luke's  
14:19:08 6 Hospital change its laboratory reference range to  
14:19:12 7 anything other than .8 to 2?

14:19:15 8 A. No.

14:19:16 9 Q. Okay. Let's go to this admission from  
14:19:29 10 January of 2008. Why was she admitted to the  
14:19:37 11 hospital on January 22nd, 2008?

14:19:45 12 A. I may be wrong, but I believe her main  
14:19:50 13 symptoms were shortness of breath, nausea; her chief  
14:20:01 14 complaint.

14:20:04 15 Q. Were you the admitting physician?

14:20:10 16 A. I can't remember. It would be in the --

14:20:16 17 Q. Well, let me withdraw it.

14:20:18 18 Was she admitted to your service?

14:20:20 19 A. Yes.

14:20:21 20 Q. And obviously at that time, you knew  
14:20:23 21 what her medication regimen was, correct?

14:20:27 22 A. I can't remember if I was the one who  
14:20:32 23 actually admitted her or not.

14:20:33 24 Q. All right. Well, let's go back to this  
14:20:39 25 January 23rd, 2008, digoxin. According to your



Reynolds M. Delgado III, M.D.

Page 120

14:20:44 1 chart, what was the time of the last dose?

14:20:48 2 A. 0013.

14:21:01 3 Q. What time was this lab of 1.2 drawn?

14:21:04 4 A. 0021.

14:21:05 5 Q. That's eight minutes later; is that

14:21:11 6 correct?

14:21:11 7 A. Yes.

14:21:11 8 Q. And I think you told me earlier that the

14:21:19 9 optimal time to draw for reliable serum digoxin

14:21:23 10 concentrations is six to eight hours later, correct?

14:21:27 11 A. Yes.

14:21:27 12 Q. Now, when she was admitted on

14:21:44 13 January 22nd, 2008, was she on any medications that

14:21:51 14 could potentially increase serum digoxin

14:21:57 15 concentrations?

14:21:58 16 A. Not that I remember. I could look at

14:22:07 17 her list, if you have it, from admit.

14:22:41 18 Q. She was on digoxin, spironolactone,

14:22:45 19 Vicodin, hydrochlorothiazide, metoprolol, potassium,

14:22:54 20 lisinopril, Primacor, Lasix and Coreg.

14:22:59 21 A. Okay. I wouldn't expect any of those to

14:23:05 22 increase the blood levels.

14:23:06 23 Q. Does the medical literature indicate

14:23:07 24 that several of those medications have the potential

14:23:11 25 to increase serum digoxin levels?

Reynolds M. Delgado III, M.D.

Page 121

14:23:15 1 A. The medical literature, no. That's --  
14:23:30 2 it is not my belief that those medicines in this  
14:23:35 3 patient in this circumstance could increase the drug  
14:23:38 4 levels.

14:23:39 5 Q. Okay. All right. I understand what  
14:23:40 6 you're saying about this patient, this circumstance.  
14:23:42 7 I'm asking whether the medical literature, including  
14:23:46 8 the product labels for several of those, indicate  
14:23:49 9 that they have the potential to increase serum  
14:23:52 10 digoxin levels.

14:23:54 11 A. That's my point: You can't make that  
14:23:57 12 conclusion based on the medical literature. The  
14:24:01 13 medical literature applies to the population, not a  
14:24:05 14 particular patient at a particular point in time.

14:24:07 15 Q. Okay. I'm just asking whether the  
14:24:08 16 medical literature says that those have the  
14:24:10 17 potential to increase serum digoxin concentrations.

14:24:13 18 A. I don't know.

14:24:14 19 Q. And why is it your opinion that none of  
14:24:17 20 those medications increased her serum digoxin  
14:24:21 21 concentration, if it was, in fact, elevated?

14:24:24 22 A. Because the medicines that increase  
14:24:29 23 digoxin levels are medicines that interfere with its  
14:24:33 24 metabolism.

14:24:34 25 Q. Okay.

Reynolds M. Delgado III, M.D.

Page 122

14:24:37 1 A. Amiodarone is the best example, and  
14:24:42 2 amiodarone roughly doubles digoxin levels. She  
14:24:47 3 wasn't on amiodarone.

14:24:48 4 Q. But have you read the Coreg product  
14:24:51 5 label?

14:24:53 6 A. Any medicine given in excess or, you  
14:24:58 7 know, in a toxic level or high level could  
14:25:01 8 theoretically do anything, but...

14:25:03 9 Q. Have you read the --

14:25:05 10 A. I haven't --

14:25:06 11 Q. Have you read the Coreg label to see  
14:25:09 12 whether it, given in normal doses, has the potential  
14:25:11 13 to increase digoxin levels?

14:25:13 14 A. I haven't read that, no.

14:25:15 15 Q. All right. So you knew when she was  
14:25:21 16 admitted, obviously, that she was on digoxin. Do  
14:25:24 17 you know what brand she was given during that  
14:25:27 18 admission and that dose on the 23rd?

14:25:34 19 A. Do I know it now, in retrospect, or did  
14:25:37 20 I know it at the time?

14:25:38 21 Q. Did you know then?

14:25:39 22 A. No.

14:25:39 23 Q. Do you know now?

14:25:40 24 A. Yes.

14:25:41 25 Q. And what was she given at 13 minutes

Reynolds M. Delgado III, M.D.

Page 123

14:25:45 1 past midnight on the 23rd?

14:25:50 2 A. I thought you asked what she had been  
14:25:51 3 on, or do you mean at that particular point in time?

14:25:53 4 Q. Do you know what she was given that  
14:25:55 5 night in the hospital?

14:25:56 6 A. No.

14:25:57 7 Q. All right. And you discharged Mrs. Vega  
14:26:04 8 on January 25th, 2008, correct?

14:26:07 9 A. I don't remember if it was me,  
14:26:12 10 specifically. Again, we have this rounding team  
14:26:17 11 that deals with inpatients in the hospital. It may  
14:26:20 12 or may not have been me.

14:26:21 13 Q. Who does Patricia Aldridge, R.N., work  
14:26:27 14 for?

14:26:27 15 A. She is a nurse at the hospital.

14:26:29 16 Q. Well, this discharge summary lists you  
14:26:32 17 as the attending physician?

14:26:34 18 A. Yes.

14:26:34 19 Q. Okay. Now, did you diagnose Mrs. Vega  
14:26:36 20 with cardiogenic shock in the admission between  
14:26:39 21 January 22nd and 25th, 2008?

14:26:44 22 A. I don't remember.

14:26:46 23 Q. Well, I have the discharge summary in  
14:26:48 24 front of me, and it's not any of the six listed  
14:26:52 25 diagnoses. Do you have any other reason to think

Reynolds M. Delgado III, M.D.

Page 124

14:26:57 1 that you diagnosed her with cardiogenic shock during  
14:27:01 2 that admission?

14:27:02 3 A. No.

14:27:02 4 Q. And despite knowing she was on digoxin  
14:27:13 5 and that she had a level of 1.2, nowhere in the  
14:27:17 6 medical records between January 22nd and 25th, 2008,  
14:27:21 7 did you attribute any of her problems to excessive  
14:27:27 8 digoxin, correct?

14:27:32 9 A. I'm sorry, please repeat. I didn't  
14:27:41 10 catch that.

14:27:41 11 Q. Sure.

14:27:42 12 Do you know of any entries in the  
14:27:46 13 medical record between January 22nd and  
14:27:50 14 January 25th, 2008, to indicate that her problems at  
14:27:57 15 the time were attributable to digoxin?

14:28:08 16 A. At the time, no.

14:28:09 17 Q. Okay. Now, Mrs. Vega was then  
14:28:25 18 readmitted on January 31st, correct?

14:28:29 19 A. Yes.

14:28:30 20 Q. What was the purpose of that admission?

14:28:33 21 A. If I could refer to the admission note  
14:28:39 22 or the ER note, I could better answer that.

14:28:41 23 Q. Well, the chief complaint is shortness  
14:28:43 24 of breath, nausea, vomiting and weakness. Did you  
14:28:47 25 attribute that, at the time, to digoxin problems?

Reynolds M. Delgado III, M.D.

Page 125

14:28:53 1 A. No.

14:28:55 2 Q. Did anybody even draw a serum digoxin  
14:29:00 3 concentration between admission and when she went to  
14:29:05 4 the cath lab for her catheterization and intraaortic  
14:29:12 5 balloon pump procedure?

14:29:14 6 A. I don't know. I know I didn't.

14:29:22 7 Q. What was the purpose of the February 5th  
14:29:26 8 catheterization and intraaortic balloon pump  
14:29:31 9 procedure?

14:29:39 10 A. At that point, I believe I had  
14:29:41 11 determined she was in cardiogenic shock; and the  
14:29:43 12 purpose was to reverse that, improve that.

14:29:47 13 Q. Okay. At the time, what was your  
14:29:49 14 diagnosis of the cause of her cardiogenic shock?

14:29:53 15 A. At the time, my diagnosis was  
14:30:03 16 cardiogenic shock.

14:30:05 17 Q. Yeah. But did you have a diagnosis as  
14:30:08 18 to the cause of the cardiogenic shock?

14:30:09 19 A. I don't know. I may -- maybe I'll  
14:30:18 20 explain it a little different. Cardiogenic shock is  
14:30:20 21 the problem; it's not the cause of the problem.

14:30:25 22 Q. But something usually causes the  
14:30:28 23 problem, so what caused the problem known as  
14:30:31 24 cardiogenic shock?

14:30:33 25 A. In her case, her heart failure changed

Reynolds M. Delgado III, M.D.

Page 126

14:30:41 1 to become cardiogenic shock.

14:30:44 2 Q. Okay. And at the time, did you have a  
14:30:47 3 diagnosis, to a reasonable degree of medical  
14:30:51 4 probability, or a theory, to a reasonable degree of  
14:30:53 5 medical probability, as to why her heart failure  
14:30:57 6 changed to tip her into cardiogenic shock?

14:31:00 7 A. At the time, no.

14:31:01 8 Q. You were the admitting physician for  
14:31:07 9 this admission, correct?

14:31:09 10 A. Yes.

14:31:09 11 Q. You had all this data available to you?

14:31:11 12 A. Yes.

14:31:13 13 Q. And if I understand what you told me  
14:31:30 14 before, if you were suspicious that digoxin was  
14:31:35 15 causing a patient clinical problems, you had the  
14:31:37 16 ability to order serum digoxin levels, correct?

14:31:42 17 A. Yes.

14:31:42 18 Q. And if there are no such levels in this  
14:31:45 19 chart prior to the cath and the IABP, would it be  
14:31:51 20 safe for me to assume that you weren't suspicious  
14:31:54 21 that digoxin was causing her clinical problems?

14:31:56 22 A. No.

14:31:57 23 Q. Well, then, why didn't you order SDCs?

14:32:01 24 A. I never do. It's irrelevant.

14:32:03 25 Q. Did you write anywhere in the -- it's

Reynolds M. Delgado III, M.D.

Page 127

14:32:06 1 irrelevant?

14:32:06 2 A. Absolutely.

14:32:07 3 Q. Okay. Did you --

14:32:09 4 A. At the time, it was absolutely  
14:32:10 5 irrelevant to order it.

14:32:11 6 Q. Did you write anywhere in the chart that  
14:32:15 7 prior --

14:32:15 8 A. I know it's confusing, but I can  
14:32:18 9 explain.

14:32:18 10 Q. Okay. Explain.

14:32:19 11 A. You don't order a test that you do not  
14:32:22 12 plan on acting upon. That's a simple way to explain  
14:32:26 13 it.

14:32:27 14 Q. Well, wouldn't you want to know whether  
14:32:29 15 she had an elevated level or not?

14:32:31 16 A. Again, you don't order a test in which  
14:32:34 17 you don't plan to act on.

14:32:36 18 Q. Well, what if --

14:32:38 19 A. There can actually be downsides to doing  
14:32:40 20 so.

14:32:40 21 Q. What if --

14:32:41 22 A. Again, it goes back to that same maxim  
14:32:45 23 of bad data is worse than no data.

14:32:48 24 Q. Well, what if the level was high enough  
14:32:50 25 that you should order Digibind, how would you know?



Reynolds M. Delgado III, M.D.

Page 128

14:32:54 1 A. You do not ever order Digibind based on

14:32:58 2 a level.

14:32:58 3 Q. What do you order Digibind based on?

14:32:59 4 A. That's stupid.

14:32:59 5 Q. Okay. What do you order Digibind --

14:33:02 6 A. You don't ever order anything based on a

14:33:05 7 number that comes across a computer screen.

14:33:07 8 Q. Have you ever ordered Digibind?

14:33:10 9 A. Never.

14:33:10 10 Q. Okay. Well, if the level was .2 or .3

14:33:14 11 or even .5, wouldn't you want to know that?

14:33:18 12 A. At the time, it's not necessary, as I

14:33:19 13 just explained.

14:33:20 14 Q. Okay.

14:33:20 15 A. It's irrelevant and it could, in fact,

14:33:22 16 be harmful.

14:33:23 17 Q. All right. Were there any serum digoxin

14:33:26 18 levels drawn between when you took her to the cath

14:33:29 19 lab on the 5th and February 28th, when this next

14:33:35 20 level was drawn?

14:33:36 21 A. Meaning other than on these graphs?

14:33:45 22 Q. Well, there is no result for

14:33:47 23 February 8th, so --

14:33:49 24 A. I -- not to my knowledge.

14:33:51 25 Q. Okay. So why was there a level drawn on

Reynolds M. Delgado III, M.D.

Page 129

14:33:54 1 February 28th?

14:33:55 2 A. I don't know. Unfortunately, the house  
14:34:02 3 staff have a tendency to do such things.

14:34:09 4 Q. So if you didn't order that level, I  
14:34:19 5 would assume that your thought process at the time  
14:34:22 6 would have been that it wasn't relevant to your  
14:34:24 7 management, correct?

14:34:25 8 A. As I explained earlier, it's gathering  
14:34:29 9 data that could be of only harm to the patient.

14:34:32 10 Q. Okay. Do you know whether, on and after  
14:34:38 11 February 28th, the patient continued to get digoxin?

14:34:43 12 A. Yes. At some point in the future after  
14:34:46 13 that, she received it. I don't know what the exact  
14:34:49 14 time is.

14:34:49 15 Q. So you don't know whether she got it on  
14:34:52 16 the 28th? I mean, it appears she was getting it on  
14:34:55 17 the 28th, correct?

14:34:59 18 A. I'm not sure what you're looking at,  
14:35:01 19 but --

14:35:01 20 Q. In your chart at this graph, I'm looking  
14:35:03 21 at this lab that indicates --

14:35:06 22 MR. WILLIAMSON: Well, just for the  
14:35:07 23 record, you're at one end of the table, he's at the  
14:35:09 24 other end of the table. So when you say "your  
14:35:12 25 chart," you're talking about multiple, multiple

Reynolds M. Delgado III, M.D.

Page 130

14:35:15 1 pages.

14:35:16 2 MR. MORIARTY: The black binder that

14:35:18 3 we've been looking at --

14:35:19 4 THE WITNESS: Which number?

14:35:19 5 MR. WILLIAMSON: Do you have a Bates

14:35:20 6 number?

14:35:20 7 MR. MORIARTY: Sure. It's MVDCA:27.

14:35:27 8 MR. WILLIAMSON: MVDCA?

14:35:27 9 MR. MORIARTY: 27.

14:35:28 10 MR. WILLIAMSON: 27. Thank you.

14:35:28 11 THE WITNESS: And the question,

14:35:29 12 again, is?

14:35:29 13 MR. MORIARTY: Okay.

14:35:29 14 BY MR. MORIARTY:

14:35:29 15 Q. You see the level for February 28th,

14:35:32 16 2008 --

14:35:32 17 A. Yes.

14:35:32 18 Q. -- of 1.2, correct?

14:35:34 19 A. Correct.

14:35:35 20 Q. And it has a draw time and a last dose

14:35:40 21 time, correct?

14:35:40 22 A. Yes.

14:35:40 23 Q. Do you know whether anyone discontinued

14:35:42 24 her digoxin in the face of this 1.2?

14:35:44 25 A. I don't know.

Reynolds M. Delgado III, M.D.

Page 131

14:35:45 1 Q. Well, if some -- if a physician believed  
14:35:50 2 that a level of 1.2 was reflective of some clinical  
14:35:57 3 problems that she was having as a result of digoxin,  
14:36:01 4 would the appropriate step to have been to  
14:36:04 5 discontinue the digoxin?

14:36:06 6 A. Can you remind me of the date she had  
14:36:11 7 the LVAD, the initial Jarvik 2000?

14:36:22 8 Q. February 11th. No, I'm sorry. Yes,  
14:36:22 9 February 11th, 2008.

14:36:24 10 A. All right. So the answer is: It's  
14:36:25 11 irrelevant.

14:36:25 12 Q. What's irrelevant?

14:36:27 13 A. What -- whether she's on digoxin or not  
14:36:30 14 and what her levels are.

14:36:34 15 Q. Well, so what her -- if what her levels  
14:36:40 16 are is irrelevant --

14:36:42 17 A. At the time. Currently -- obviously in  
14:36:44 18 retrospect, it's not. It tells us what the problem  
14:36:47 19 is, why she died.

14:36:50 20 Q. Well, let me make sure I understand  
14:36:52 21 this. There's a team of cardiologists and residents  
14:36:58 22 and pulmonologists and heart surgeons attending to  
14:37:02 23 this woman who's now had the placement of a left  
14:37:08 24 ventricular assist device, correct?

14:37:09 25 A. Correct.

Reynolds M. Delgado III, M.D.

Page 132

14:37:09 1 Q. All right. At the Texas Heart Institute  
14:37:11 2 and St. Luke's Hospital, correct?

14:37:13 3 A. Yes.

14:37:13 4 Q. A very, very reputable heart-care team,  
14:37:22 5 correct?

14:37:22 6 A. Yes.

14:37:22 7 Q. And this heart-care team presumably  
14:37:28 8 knows what the potential signs, symptoms and lab  
14:37:38 9 abnormalities are to problems with digoxin, correct?

14:37:43 10 A. Yes.

14:37:44 11 Q. All right. And presumably, the team was  
14:37:50 12 aware of the February 28th, 2008, level of 1.2,  
14:37:54 13 correct?

14:37:55 14 A. Yes. They were also aware that she had  
14:37:59 15 an LVAD on the 11th.

14:38:01 16 Q. Right.

14:38:02 17 But if somebody -- hypothetically,  
14:38:06 18 if somebody was concerned about a level of 1.2 on  
14:38:11 19 February 28th, they could have discontinued the  
14:38:15 20 digoxin, correct?

14:38:16 21 A. I wouldn't expect that somebody to be  
14:38:21 22 somebody on my team.

14:38:23 23 Q. Well, if digoxin was theoretically  
14:38:26 24 causing a problem on February 28th, why would the  
14:38:31 25 drug be continued?

Reynolds M. Delgado III, M.D.

Page 133

14:38:34 1 A. If it was causing a problem, then why  
14:38:36 2 wouldn't it be continued?

14:38:39 3 Q. No. Why would it be continued?

14:38:43 4 If somebody suspects that digoxin is  
14:38:46 5 causing a problem on February 28th, why would they  
14:38:48 6 continue the medication?

14:38:52 7 A. I can't speak for somebody. I know, in  
14:38:54 8 retrospect, that it caused the problem. At the  
14:38:59 9 time, I don't think anybody did, nor was it relevant  
14:39:03 10 after she got the LVAD.

14:39:07 11 Q. So you're saying, in retrospect, a lot  
14:39:09 12 of people overlooked some important data that was in  
14:39:13 13 the medical records?

14:39:14 14 A. Absolutely not.

14:39:17 15 Q. Okay.

14:39:17 16 A. In retrospect, they came to the  
14:39:23 17 understanding or knowledge that she was being  
14:39:26 18 overdosed on the drug; and, of course, what we see  
14:39:28 19 here are steady-state trough levels, in  
14:39:32 20 pharmacologic terms.

14:39:33 21 Q. Okay.

14:39:33 22 A. Does that confuse you?

14:39:35 23 Q. But I think what you told me before --

14:39:36 24 A. Okay.

14:39:37 25 Q. -- just because there's an elevated

Reynolds M. Delgado III, M.D.

Page 134

14:39:39 1 level doesn't mean that the dose is too high,  
14:39:41 2 correct?

14:39:41 3 A. You don't understand that at all. Basic  
14:39:44 4 Pharmacology 101. We can talk after you understand  
14:39:48 5 something, because, I'm sorry, but I can't explain  
14:39:56 6 basic pharmacology to you. It would take all week.  
14:40:00 7 You would have to have a -- you'd have to have some  
14:40:03 8 preparatory understanding first.

14:40:06 9 Q. All right. Didn't we establish earlier  
14:40:08 10 that just because there's an elevated level, you  
14:40:11 11 would want to look for the causes of the elevated  
14:40:14 12 level, correct?

14:40:16 13 A. We established the opposite.

14:40:19 14 Q. That if there's an elevated level, you  
14:40:23 15 don't look for a cause?

14:40:23 16 A. No.

14:40:24 17 Q. No, you don't look for a cause, or no,  
14:40:27 18 we didn't discuss it?

14:40:27 19 A. We don't treat numbers. You treat the  
14:40:29 20 patient.

14:40:29 21 MR. WILLIAMSON: Wait, wait, wait.  
14:40:30 22 Stop. He has asked you another question.

14:40:36 23 THE WITNESS: He --

14:40:37 24 MR. WILLIAMSON: Wait. He asked you  
14:40:38 25 another question before you finished your answer.

Reynolds M. Delgado III, M.D.

Page 135

14:40:41 1 You answered kind of in like kind. Let's go back to  
14:40:44 2 a system where you finish your question, and make  
14:40:47 3 sure he finishes his answer.

14:40:49 4 MR. MORIARTY: Sure.

14:40:50 5 BY MR. MORIARTY:

14:40:50 6 Q. If you don't treat numbers  
14:40:52 7 prospectively, what is the methodology that you are  
14:40:58 8 using to now retrospectively say that this was a  
14:41:04 9 cause of a problem?

14:41:06 10 A. Because we see an elevated steady-state  
14:41:12 11 trough level of digoxin.

14:41:16 12 Q. Which means what?

14:41:17 13 A. Basic pharmacology. I'm sorry, I can't  
14:41:21 14 explain that.

14:41:21 15 Q. No. What does it mean?

14:41:22 16 A. I can tell you this. Let me help you  
14:41:25 17 with this piece of it. If you give someone a dose  
14:41:28 18 of digoxin now, their level will go way up and it  
14:41:32 19 will come down. If you give them a dose every  
14:41:35 20 single day, you will have a steady level a month  
14:41:43 21 later. A month later, not that day. A month later.  
14:41:52 22 That's the model of distribution of digoxin and how  
14:41:57 23 it works. That's basic pharmacology.  
14:41:59 24 We're seeing a steady-state trough  
14:42:02 25 level.



Reynolds M. Delgado III, M.D.

Page 136

14:42:02 1 Q. So what conclusion do you now draw, in  
14:42:06 2 retrospect, from the level on the 28th of February,  
14:42:13 3 2008?

14:42:16 4 A. That over a prolonged period of time,  
14:42:18 5 she had been getting too much digoxin, and that led  
14:42:26 6 to cardiogenic shock.

14:42:28 7 Q. And why did no one diagnose that link in  
14:42:43 8 February of 2008?

14:42:45 9 A. Because no one had a reason to believe  
14:42:47 10 in February 2008 that the pills were tainted.

14:42:52 11 Q. Okay. So at the time, somebody must  
14:43:05 12 have attributed the 1.2 to something other than a  
14:43:11 13 tainted tablet?

14:43:15 14 A. At the time, I didn't attribute the 1.2  
14:43:20 15 to anything. Again, it's irrelevant, particularly  
14:43:24 16 the second one, when she had the LVAD.

14:43:26 17 Q. I just don't understand why it's  
14:43:28 18 irrelevant then but relevant now. Can you explain  
14:43:31 19 that to me?

14:43:32 20 A. I already have. I'm sorry, but I can't  
14:43:35 21 keep restating myself.

14:43:36 22 Q. Okay. So have you ever seen any tests  
14:43:54 23 of Mimi Rivera-Vega's Digitek tablets to indicate  
14:44:00 24 they were outside the label specifications?

14:44:02 25 A. No.

Reynolds M. Delgado III, M.D.

Page 137

14:44:02 1 Q. Have you -- did St. Luke's Hospital  
14:44:05 2 gather samples of Digitek and submit them for lab  
14:44:10 3 analysis to see if they were outside specifications?

14:44:12 4 A. I don't know.

14:44:12 5 Q. And you didn't personally do that or  
14:44:17 6 weigh or measure any of them, correct?

14:44:19 7 A. Correct.

14:44:19 8 Q. So do you have any actual evidence to  
14:44:23 9 indicate that a single tablet, much less more than  
14:44:27 10 one, that she ever got anywhere was outside the  
14:44:31 11 label specifications?

14:44:36 12 A. As far as I know, the Courts and the  
14:44:37 13 police have the evidence. I'm not an evidence -- I  
14:44:45 14 don't carry evidence or create evidence.

14:44:46 15 Q. Oh, I understand that. I'm just -- so  
14:44:51 16 assuming -- well, are you only basing --

14:44:55 17 MR. WILLIAMSON: How could he  
14:44:56 18 possibly know what's in a pill that she took? How  
14:44:58 19 could you possibly test a pill that she took from  
14:45:02 20 November 1st of '07 to January 23rd, '08? Now, how  
14:45:06 21 could we possibly test that pill? She ingested the  
14:45:10 22 pill.

14:45:10 23 MR. MORIARTY: Okay.

14:45:12 24 BY MR. MORIARTY:

14:45:12 25 Q. At any point after the recall in April

Reynolds M. Delgado III, M.D.

Page 138

14:45:14 1 of 2008, did St. Luke's Hospital gather up samples  
14:45:18 2 of Digitek and have them tested?

14:45:20 3 A. I'm sorry, I can't answer that. You're  
14:45:25 4 asking the wrong person.

14:45:26 5 Q. Okay. So is it -- am I to understand  
14:45:30 6 that the only evidence that you have today to  
14:45:35 7 suspect in retrospect that she got, as you called  
14:45:39 8 them, tainted pills, is the fact that there was a  
14:45:41 9 recall?

14:45:43 10 MR. WILLIAMSON: No, don't answer  
14:45:44 11 that question. He can rephrase that.

14:45:47 12 He doesn't have evidence. It's not  
14:45:49 13 his job. Courts have evidence.

14:45:51 14 MR. MORIARTY: I'm sorry, but  
14:45:52 15 he's --

14:45:53 16 MR. WILLIAMSON: You can ask him  
14:45:54 17 about any medical opinion he holds. You can ask him  
14:45:56 18 the basis for that medical opinion. You can him  
14:45:58 19 about any facts he's aware of. He is not the  
14:46:00 20 repository of what is called evidence, because that  
14:46:02 21 is a court term.

14:46:03 22 MR. MORIARTY: Okay.

14:46:04 23 MR. WILLIAMSON: I think even you  
14:46:06 24 will agree with me that medical doctors don't deal  
14:46:07 25 in terms of evidence the way you and I do.

Reynolds M. Delgado III, M.D.

Page 139

14:46:10 1 MR. MORIARTY: I disagree. They  
14:46:12 2 deal with scientific evidence.

14:46:14 3 THE WITNESS: And, also, you can't  
14:46:16 4 asked me to restate myself over and over again.  
14:46:18 5 I've answered the question.

14:46:19 6 MR. WILLIAMSON: He'll ask you  
14:46:20 7 another question.

14:46:21 8 MR. MORIARTY: I don't think you  
14:46:22 9 have.

14:46:22 10 BY MR. MORIARTY:

14:46:22 11 Q. But do you have an opinion today, to a  
14:46:24 12 reasonable degree of medical probability, as to what  
14:46:29 13 caused Mimi Rivera-Vega to go into cardiogenic shock  
14:46:35 14 in February 2008?

14:46:39 15 A. That's the right question.

14:46:41 16 Yes, I do.

14:46:42 17 Q. What's your opinion, to a reasonable  
14:46:44 18 degree of medical probability?

14:46:46 19 A. I've already answered it.

14:46:48 20 Q. What is your opinion, to a reasonable  
14:46:49 21 degree of medical probability?

14:46:51 22 MR. WILLIAMSON: Answer again.

14:46:52 23 THE WITNESS: Okay.

14:46:54 24 A. She got, and subsequently ingested, a  
14:47:05 25 tablet of digoxin which was an inappropriate dose,

Reynolds M. Delgado III, M.D.

Page 140

14:47:13 1 and it led to her cardiogenic shock and ultimate  
14:47:15 2 death.

14:47:16 3 BY MR. MORIARTY:

14:47:17 4 Q. Are you done with your answer?

14:47:17 5 A. Over a period of time, actually. It was  
14:47:20 6 not the single pill. Again, it takes a long time to  
14:47:26 7 reach steady-state.

14:47:28 8 Q. What's the basis for that opinion?

14:47:30 9 A. Which part?

14:47:36 10 Q. Your opinion that she got digoxin  
14:47:41 11 tablets that were out of specification.

14:47:47 12 A. My opinion was generated in retrospect  
14:47:51 13 by reviewing the chart and seeing -- I think I used  
14:47:59 14 the word earlier -- help me -- "sign," maybe,  
14:48:08 15 "clue"? Maybe I used the word "clue" -- in these  
14:48:12 16 two digoxin levels, 1/23/08 to 2/28/08, and putting  
14:48:19 17 the entire clinical picture together, the fact that  
14:48:21 18 she had been stone-cold stable with stable  
14:48:26 19 compensated congestive heart failure over a period  
14:48:30 20 of -- you know, since '02, and then fell off the  
14:48:34 21 cliff at this point in time.

14:48:37 22 Q. Fell off the cliff when?

14:48:42 23 A. Late January, early February.

14:48:45 24 Q. How many out-of-spec digoxin tablets did  
14:48:51 25 Mimi get?

Reynolds M. Delgado III, M.D.

Page 141

14:48:51 1 A. I don't know.

14:48:52 2 Q. How many -- how far out of specification  
14:48:55 3 were they?

14:48:55 4 A. I don't know.

14:48:59 5 Q. Between the catheterization and the  
14:49:30 6 IABP, did you ever draw any serum digoxin levels?

14:49:34 7 A. No.

14:49:34 8 Q. What was the purpose of the left  
14:49:39 9 ventricular assist device?

14:49:42 10 A. To treat her cardiogenic shock.

14:49:45 11 Q. And bridge-to-transplant?

14:49:52 12 A. At the time, it was to treat her  
14:49:54 13 cardiogenic shock.

14:49:55 14 Q. Okay. In the February 11th records  
14:49:59 15 surrounding this LVAD placement, there's a comment  
14:50:02 16 about enrollment in some LVAD study. Were you doing  
14:50:06 17 an LVAD study in February of 2008?

14:50:09 18 A. Yes.

14:50:09 19 Q. I'd like you to check your records and  
14:50:11 20 see if she was enrolled, please.

14:50:14 21 A. I don't need to. I can tell you what it  
14:50:16 22 is.

14:50:17 23 Q. Well, can you tell me whether she was  
14:50:20 24 actually enrolled?

14:50:21 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 142

14:50:21 1 Q. All right. Was she?

14:50:22 2 A. Yes.

14:50:22 3 Q. And what was the study?

14:50:24 4 A. Jarvik 2000.

14:50:27 5 Q. Is there a file on her for her

14:50:31 6 Jarvik 2000 trial?

14:50:33 7 A. I don't know. The Jarvik 2000 remains

14:50:38 8 in trial. It was then; it is now. It's a trial,

14:50:42 9 study device.

14:50:43 10 Q. In your opinion, to a probability, would

14:50:45 11 she have needed a Jarvik 2000 or comparable at some

14:50:50 12 point?

14:50:51 13 A. I had hoped to primarily transplant her.

14:50:57 14 Q. Okay. Well, if there wasn't a heart

14:51:02 15 available and she needed further bridging, so to

14:51:06 16 speak, that Jarvik or comparable would be the mode

14:51:11 17 of therapy, correct?

14:51:12 18 A. Yes.

14:51:12 19 Q. Who is Dr. Frazier?

14:51:47 20 A. The chief of cardiopulmonary

14:51:52 21 transplantation, the Texas Heart Institute.

14:51:56 22 MR. WILLIAMSON: The gentleman who's

14:51:58 23 performed more heart transplants than any other

14:52:01 24 individual on earth.

14:52:01 25 BY MR. MORIARTY:

Reynolds M. Delgado III, M.D.

Page 143

14:52:02 1 Q. Do you know whether Dr. Frazier, at any  
14:52:03 2 point, made a diagnosis that her cardiogenic shock  
14:52:05 3 and the need for this LVAD was based on some digoxin  
14:52:08 4 problem?

14:52:10 5 A. I don't know.

14:52:13 6 Q. Did he ever write that in the record?

14:52:16 7 A. Not that I know of.

14:52:18 8 Q. Would you assume that he had all the  
14:52:20 9 same data available that you did at the time?

14:52:22 10 A. Yes.

14:52:22 11 (Delgado Deposition Exhibit 7  
14:52:22 12 marked.)

14:52:22 13 (Delgado Deposition Exhibit 8  
14:52:22 14 marked.)

14:52:22 15 BY MR. MORIARTY:

14:52:22 16 Q. On February 23rd -- let me just show you  
14:52:43 17 these two exhibits. These are Exhibits 7 and 8. On  
14:52:47 18 7, I'll tell you that this was February 4th, 2008.  
14:52:51 19 Is this your handwriting?

14:52:52 20 A. Yes.

14:52:52 21 Q. Does that say, "Poor prognostic  
14:52:58 22 features, prep for VAD"?

14:52:59 23 A. Yes.

14:53:03 24 MR. MORIARTY: All right. Hunter,  
14:53:04 25 could you make sure you separate out the exhibits?



Reynolds M. Delgado III, M.D.

Page 144

14:53:06 1 They're starting to get mixed up.

14:53:15 2 BY MR. MORIARTY:

14:53:16 3 Q. This is Exhibit 8. It is a note. Is  
14:53:22 4 this your handwriting?

14:53:25 5 A. Parts of it.

14:53:26 6 Q. Okay. At the bottom, it says, "Patient  
14:53:29 7 listed for transplant as status of 1-A by  
14:53:34 8 St. Luke's" --

14:53:34 9 A. "Medical review board."

14:53:36 10 Q. All right.

14:53:37 11 MR. WILLIAMSON: You got a  
14:53:38 12 Bates-stamp number you can give me, because I  
14:53:40 13 don't --

14:53:41 14 MR. MORIARTY: MVSLE:3523. It's  
14:53:48 15 from the St. Luke's chart.

14:53:49 16 MR. WILLIAMSON: Thanks.

14:53:51 17 BY MR. MORIARTY:

14:53:52 18 Q. First of all, is there probably a  
14:53:54 19 separate file regarding her transplant approval  
14:53:57 20 process?

14:53:57 21 A. It would contain the same information.  
14:54:06 22 There may be a separate file with bits and pieces of  
14:54:12 23 all this somewhere.

14:54:13 24 Q. Okay. Where would that file be?

14:54:15 25 A. At the transplant office.

Reynolds M. Delgado III, M.D.

Page 145

14:54:16 1 Q. All right. And what are the criteria  
14:54:18 2 for status 1-A?

14:54:20 3 A. The UNOS criteria are -- can be read on  
14:54:28 4 the United Network for Organ Sharing website. It's  
14:54:33 5 very complicated.

14:54:36 6 Q. But I can look on there and figure it  
14:54:38 7 out, right?

14:54:38 8 A. Yeah.

14:54:38 9 Q. Okay. On February 23rd, did you start  
14:54:43 10 Mimi on digoxin also for atrial fibrillation?

14:54:50 11 A. I don't remember.

14:54:50 12 Q. Assuming that's noted in the chart, what  
14:54:53 13 was the cause of her a-fib?

14:54:56 14 A. I don't remember specifically, but she  
14:55:06 15 develops right heart failure, unfortunately, after  
14:55:10 16 receiving the LVAD, and that caused a number of  
14:55:12 17 problems, which the a-fib may have been one.

14:55:17 18 Q. Do you know, when she was started on  
14:55:21 19 February 23rd, whether she was started on IV  
14:55:26 20 digoxin?

14:55:30 21 A. I don't know. I'd have to look it up.

14:55:31 22 Q. Assuming she was, is that of any  
14:55:33 23 significance to you in the lead-up to February 28th?

14:55:38 24 A. In general, that's used for rate control  
14:55:45 25 extrapolation.

Reynolds M. Delgado III, M.D.

Page 146

14:55:45 1 Q. Well, I understand that. But if you  
14:55:46 2 draw a digoxin level on the 28th, is it going to  
14:55:49 3 reflect not only IV digoxin given, but also oral  
14:55:54 4 digoxin taken?

14:55:57 5 A. It depends on timing.

14:56:02 6 Q. What's the half-life of IV digoxin?

14:56:05 7 A. That's the problem. This is a very  
14:56:06 8 difficult volume-of-distribution drug, and it's got  
14:56:10 9 multiple volumes of distribution.

14:56:13 10 Q. Is the toxicology or pharmacokinetic  
14:56:18 11 aspect of these doses leading up to February 28th  
14:56:24 12 better answered by pharmacokineticists --

14:56:28 13 A. Probably.

14:56:29 14 Q. -- and toxicologists?

14:56:30 15 A. No, pharmacokineticists. In other  
14:56:33 16 words, you get one PK curve for a clean drug. You  
14:56:37 17 don't have that with this. This has got multiple PK  
14:56:42 18 curves, multiple volumes of distribution. The  
14:56:45 19 steady-state takes a month.

14:56:47 20 Q. All right. And maybe I am not clear on  
14:56:49 21 this, but other than the recall, do you have any  
14:56:57 22 other scientific information available to you to  
14:57:01 23 indicate that any digoxin she was given was out of  
14:57:06 24 specification?

14:57:18 25 A. I guess theoretically, you could say all

Reynolds M. Delgado III, M.D.

Page 147

14:57:20 1 this is.

14:57:21 2 MR. WILLIAMSON: Correct.

14:57:22 3 BY MR. MORIARTY:

14:57:22 4 Q. All what?

14:57:25 5 A. Everything; her entire record. In other

14:57:29 6 words, you come to a conclusion based on the

14:57:39 7 confluence of the evidence, not on a piece of it.

14:57:42 8 Q. Okay. But you did not suspect that it

14:57:48 9 might be out-of-specification digoxin until on or

14:57:56 10 after you heard about the recall, correct?

14:57:59 11 A. I never suspected it. I just found out

14:58:03 12 about the recall. I don't suspect such things

14:58:06 13 happen in a civilized country.

14:58:07 14 Q. No, I understand that.

14:58:08 15 A. I know they happen in India.

14:58:09 16 Q. But what started -- what started your

14:58:12 17 thought process to lead you to this conclusion was

14:58:14 18 on or after the recall, correct?

14:58:16 19 A. Correct.

14:58:17 20 Q. Okay. Between April 28th and when

14:58:45 21 Mrs. Vega went to the hospital -- I'm sorry, let me

14:58:49 22 withdraw that because I think I gave the wrong date.

14:58:51 23 Between February 28th and when

14:58:55 24 Mrs. Vega went to the hospital in the middle of

14:58:59 25 May 2008, did she ever have any other serum digoxin

Reynolds M. Delgado III, M.D.

Page 148

14:59:04 1 concentrations drawn?

14:59:06 2 A. Not that I know of.

14:59:24 3 Q. Does this chart, this graphic material  
14:59:26 4 that's in your office chart, MVDCA:27, 28, 29 and  
14:59:34 5 30, pick up office and hospital serum digoxin  
14:59:39 6 concentrations?

14:59:40 7 A. No, just hospital.

14:59:45 8 Q. Is there any evidence in your office  
14:59:47 9 chart that you drew serum digoxin concentrations  
14:59:51 10 between discharge on March 10th and when she was  
14:59:55 11 rehospitalized on March 17th?

15:00:01 12 A. No.

15:00:01 13 Q. Does it reflect any serum digoxin  
15:00:06 14 concentrations during the admission of March 17th to  
15:00:09 15 April 4th, 2008?

15:00:12 16 A. I'm sorry, ask the last question again.

15:00:14 17 Q. Sure.

15:00:14 18 Does your chart reflect any serum  
15:00:17 19 digoxin concentrations drawn between March 17th and  
15:00:21 20 April 4th, 2008?

15:00:22 21 A. No.

15:00:28 22 Q. And then does your office chart reflect  
15:00:36 23 any serum digoxin concentrations drawn between  
15:00:38 24 April 4th and April 22nd, when she was readmitted?

15:00:46 25 A. Not that I know of.

Reynolds M. Delgado III, M.D.

Page 149

15:00:48 1 Q. And were there any serum digoxin  
15:00:52 2 concentrations drawn between April 22 and April 25,  
15:00:56 3 when she was readmitted to St. Luke's?

15:00:59 4 A. Not that I know of.

15:01:01 5 Q. And if, hypothetically, Mrs. Vega was  
15:01:11 6 taking out-of-specification digoxin on a regular  
15:01:18 7 basis between March 10th and April 24th, would you  
15:01:27 8 expect her to have some adverse clinical signs and  
15:01:39 9 symptoms?

15:01:41 10 A. No. She had the LVAD at that period of  
15:01:47 11 time, as I remember.

15:01:48 12 Q. And how -- why does that make a  
15:01:50 13 difference?

15:01:51 14 A. Well, the LVAD gets rid of the heart  
15:01:54 15 failure.

15:01:56 16 Q. Well, digoxin doesn't cause heart  
15:01:59 17 failure. It would cause other problems, correct?

15:02:03 18 A. That's the real trick. You've got to  
15:02:06 19 read that Kirkwood Adams article to get your answer  
15:02:09 20 there.

15:02:09 21 Q. Well, in any digoxin product label, does  
15:02:13 22 it say that one of the adverse consequences of  
15:02:16 23 digoxin is heart failure?

15:02:19 24 A. It's not possible to say that because  
15:02:21 25 it's used to treat heart failure.

Reynolds M. Delgado III, M.D.

Page 150

15:02:25 1 Q. Well, if she consistently took  
15:02:31 2 out-of-specification-high Digitek or other digoxin  
15:02:34 3 products between March 10th and April 24th, would  
15:02:38 4 you have expected there to be elevated serum digoxin  
15:02:41 5 concentrations?

15:02:42 6 A. Probably not, because, again, because  
15:02:50 7 she has the LVAD.

15:02:51 8 Q. Well, does the LVAD somehow affect serum  
15:02:56 9 blood levels?

15:02:56 10 A. Absolutely.

15:02:57 11 Q. How?

15:02:58 12 A. Increases renal perfusion markedly,  
15:03:05 13 particularly in the Jarvik.

15:03:07 14 Q. Increases it beyond baseline?

15:03:10 15 A. Absolutely.

15:03:10 16 Q. So if she was taking elevated -- or  
15:03:23 17 digoxin with elevated levels of the active  
15:03:28 18 pharmaceutical ingredient post LVAD, the increased  
15:03:30 19 renal perfusion would essentially prevent her from  
15:03:34 20 having elevated levels and clinical signs and  
15:03:39 21 symptoms?

15:03:39 22 A. Likely, yes.

15:03:40 23 Q. All right. Why did her LVAD fail?

15:03:43 24 A. I don't remember the details. She  
15:03:49 25 actually had three different LVADs.

Reynolds M. Delgado III, M.D.

Page 151

15:03:52 1 Q. Well, let's just talk about the first

15:03:54 2 one --

15:03:56 3 A. Yeah.

15:03:56 4 Q. -- the Jarvik 2000 that was implanted in  
15:03:59 5 February of 2008.

15:04:03 6 A. Basically, the problem is that she had  
15:04:07 7 already fallen off the cliff, so to speak, when the  
15:04:10 8 first Jarvik was put in; so, as a result, she  
15:04:13 9 developed right heart failure. 15% of LVAD patients  
15:04:17 10 will develop right heart failure.

15:04:20 11 That led to, at some point -- I  
15:04:24 12 can't remember if it was the first or the second  
15:04:25 13 Jarvik -- aortic root thrombosis. Aortic root  
15:04:34 14 thrombosis led to the emergency need for replacement  
15:04:36 15 of the LVAD.

15:04:37 16 And so, you know, the chain of  
15:04:38 17 events started before the first Jarvik was put in.

15:04:45 18 Q. Are you done with your answer?

15:04:47 19 A. Yes.

15:04:47 20 Q. Did you ever make any adverse event  
15:04:49 21 report to the manufacturer of the Jarvik device?

15:04:54 22 A. Not me personally. The study team does.

15:04:58 23 Q. Is there a file for that adverse event  
15:05:03 24 report somewhere?

15:05:05 25 A. Likely. Likely with the FDA.



Reynolds M. Delgado III, M.D.

Page 152

15:05:08 1 Q. Who at your office would have it?

15:05:10 2 A. No one at my office. I'm not the PI on  
15:05:12 3 that trial.

15:05:13 4 Q. Whose office would have that adverse  
15:05:17 5 event report?

15:05:18 6 A. Probably the FDA.

15:05:19 7 Q. Well, the FDA's unlikely to give it to  
15:05:21 8 me.

15:05:22 9 A. Yes.

15:05:22 10 Q. Who in Houston, Texas would have it?

15:05:24 11 A. It's -- it would be, maybe, in  
15:05:29 12 cardiovascular surgery research at Texas Heart  
15:05:34 13 Institute, and they'd probably be prevented from  
15:05:36 14 giving it to you by the FDA.

15:05:40 15 Q. Were there any other AERs for any of the  
15:05:42 16 other LVADs that she received in the summer of 2008?

15:05:51 17 A. The adverse events that occurred post  
15:05:54 18 all the LVADs she received would have been  
15:05:57 19 documented and reported to the FDA very religiously.  
15:06:00 20 That's how it's done.

15:06:08 21 Q. Why did she have her first internal  
15:06:12 22 cardiac defibrillator, which I believe was in 2005?

15:06:18 23 A. It was the publishing of a critical  
15:06:24 24 clinical trial in the use of defibrillators in  
15:06:28 25 patients with low ejection fraction that led to

Reynolds M. Delgado III, M.D.

Page 153

15:06:34 1 patients being implanted around that time frame.

15:06:38 2 Probably -- there were two trials. The one that

15:06:40 3 probably was in effect at that time was the one

15:06:46 4 called MADIT II.

15:06:51 5 Q. But why was she given one?

15:06:53 6 A. That.

15:06:56 7 Q. Well, what was her clinical condition  
15:06:58 8 that warranted that device?

15:06:59 9 A. Ejection fraction less than 30.

15:07:02 10 Q. Was she part of a -- was she enrolled in  
15:07:07 11 one of those trials?

15:07:08 12 A. No. Not that I know of. She may have  
15:07:11 13 been before I took care of her.

15:07:12 14 Q. Is the risk of sudden cardiac death high  
15:07:42 15 in patients who have left ventricular dysfunction  
15:07:45 16 with an ejection fraction less than 40%?

15:07:47 17 A. It depends on whether or not they have  
15:07:50 18 an LVAD -- I mean, an ICD, defibrillator.

15:07:55 19 Q. Okay. Do you know whether she needed to  
15:08:00 20 have her ICD changed in 2005?

15:08:10 21 A. I don't remember.

15:08:10 22 Q. Did you do -- did you take her to the  
15:08:19 23 cath lab for catheterization and IABP in October of  
15:08:25 24 2007?

15:08:26 25 A. Yes.

Reynolds M. Delgado III, M.D.

Page 154

15:08:27 1 Q. Why?

15:08:28 2 A. At the time, her -- I don't remember  
15:08:40 3 what my thinking was at the time. I would have to  
15:08:43 4 go back and review the records. I just remember  
15:08:49 5 that that happened.

15:08:51 6 Q. Well, I don't have all the records, but  
15:09:01 7 I do have the op report, which is MVDCA:124, and --

15:09:08 8 MR. WILLIAMSON: MVDCA? I'm sorry.

15:09:11 9 MR. MORIARTY: MVDCA:124. And it's  
15:09:16 10 in this section of the chart, somewhere.

15:09:19 11 MR. WILLIAMSON: What's the date?  
15:09:20 12 What is it, op report?

15:09:22 13 MR. MORIARTY: It's an op report,  
15:09:24 14 10/18/07 --

15:09:26 15 MR. WILLIAMSON: Thanks.

15:09:26 16 MR. MORIARTY: -- from a right heart  
15:09:28 17 cath and placement of an IABP.

15:09:37 18 THE WITNESS: That looks like one.

15:09:39 19 BY MR. MORIARTY:

15:09:39 20 Q. Is that it?

15:09:40 21 A. Yes.

15:09:40 22 Q. Okay.

15:09:41 23 A. Yeah. Is that a different one from  
15:09:46 24 yours?

15:09:47 25 Q. Mine says -- yeah, must be. Let me look

Reynolds M. Delgado III, M.D.

Page 155

15:09:50 1 at this. Yeah. This is the one, February 5th  
15:09:54 2 of '08.

15:09:55 3 A. That's a different one.

15:09:58 4 Q. I tell you what, just look at mine.

15:10:01 5 A. Yeah.

15:10:01 6 Q. And, at least, what does the record  
15:10:06 7 indicate were the indications for that procedure?

15:10:08 8 A. Congestive heart failure, decompensated  
15:10:20 9 cardiomyopathy, cardiogenic shock.

15:10:23 10 Q. Okay. And, in your opinion, to a  
15:10:24 11 reasonable degree of medical probability, is that  
15:10:27 12 still the cause of the need for the right heart cath  
15:10:31 13 and placement of the IABP in October of '07?

15:10:34 14 A. No.

15:10:34 15 Q. What's your current opinion about the --

15:10:37 16 A. The last sentence there explains it.

15:10:42 17 Q. "Severely deranged hemodynamics. The  
15:10:46 18 patient will be admitted for management of CHF"?

15:10:49 19 A. Yes.

15:10:50 20 Q. I'm sorry, I don't understand your  
15:10:52 21 answer, then.

15:10:53 22 A. So I went into the procedure thinking  
15:10:55 23 she may have shock. After the procedure was done,  
15:10:59 24 it was determined she didn't.

15:11:02 25 Q. Okay.

Reynolds M. Delgado III, M.D.

Page 156

15:11:02 1 A. And it was CHF.

15:11:03 2 Q. Okay. And is it still your opinion that  
15:11:09 3 this procedure was necessitated because of CHF?

15:11:13 4 A. No, the procedure was done mainly to  
15:11:18 5 diagnose CHF.

15:11:24 6 Q. I guess what I'm trying to find out is  
15:11:27 7 whether you have changed your opinion in any way,  
15:11:29 8 even retrospectively, about the need for or the  
15:11:32 9 diagnosis surrounding this October 18th, 2007,  
15:11:39 10 procedure.

15:11:40 11 A. No. The last sentence, because that --  
15:11:45 12 the procedure was done to gather the hemodynamic  
15:11:48 13 data, which determined the last sentence, that she  
15:11:53 14 had heart failure --

15:11:54 15 Q. Okay. That she was --

15:11:55 16 A. -- as a consequence of deranged  
15:12:02 17 hemodynamics.

15:12:05 18 Q. All right. And what was the cause of  
15:12:06 19 her heart failure and deranged hemodynamics in  
15:12:12 20 October of 2007?

15:12:12 21 A. She had elevated pulmonary artery  
15:12:25 22 pressures. That's generally what that refers to.

15:12:31 23 Q. Is this any indication that her heart  
15:12:33 24 function was worsening in the fall of 2007?

15:12:37 25 A. No.

Reynolds M. Delgado III, M.D.

Page 157

15:12:37 1 Q. Let's just take the end of calendar year  
15:13:21 2 2007 as a convenient time point, okay?

15:13:26 3 A. Uh-huh.

15:13:26 4 Q. At that point, did you have an opinion  
15:13:28 5 to a probability as to how long she could go before  
15:13:31 6 she was going to need -- on her medical management,  
15:13:36 7 before she was going to need a heart transplant?

15:13:38 8 A. My belief is, at that point, say, you  
15:13:45 9 know, December '07, was that she would remain the  
15:13:53 10 same way she had been up until that point, so '02  
15:13:58 11 to '07.

15:14:03 12 Q. Either it's been too long a day or I  
15:14:05 13 didn't understand your answer.

15:14:06 14 Looking at the end of 2007, how long  
15:14:10 15 into the future would she likely have gone on  
15:14:13 16 medical management before the need for the  
15:14:16 17 transplant?

15:14:18 18 A. There's no way to predict that,  
15:14:19 19 obviously; but my belief at the end of '07 would not  
15:14:26 20 have been substantially different than my belief  
15:14:31 21 in '02, for example.

15:14:35 22 MR. WILLIAMSON: I'm kind of falling  
15:14:36 23 down on the job. I'm ready to take a break when you  
15:14:39 24 get ready.

15:14:40 25 MR. MORIARTY: I'll be there in a

Reynolds M. Delgado III, M.D.

Page 158

15:14:41 1 minute.

15:14:41 2 MR. WILLIAMSON: Okay.

15:14:42 3 BY MR. MORIARTY:

15:14:42 4 Q. But at least as of the end of '07, there  
15:14:44 5 were actual things moving along in the direction of  
15:14:50 6 transplant, such as getting her BMI down, the  
15:14:55 7 bridge-to-transplant goal therapy of milrinone,  
15:14:58 8 things of that nature, things you weren't doing back  
15:15:00 9 in '02, right?

15:15:04 10 A. I think I was doing -- I mean, I was  
15:15:06 11 doing that in '02. I was trying to get her to lose  
15:15:09 12 weight, particularly. That was the primary problem.

15:15:12 13 Q. Well, I understand.

15:15:12 14 A. In '02, she weighed a lot more than she  
15:15:15 15 did in '07. That was the big issue. And so as her  
15:15:18 16 weight came down, as she got closer to '07, she  
15:15:23 17 became a more and more better candidate; and so that  
15:15:27 18 changed, to some degree.

15:15:40 19 MR. MORIARTY: Just give me a couple  
15:15:41 20 more minutes, and then we'll be fine to take a  
15:15:48 21 break. And I don't think I'm going to be that much  
15:15:50 22 longer after the break, anyway.

15:15:53 23 MR. WILLIAMSON: How about you?

15:15:54 24 MS. AHERN: I only have a few  
15:15:56 25 follow-up questions.

Reynolds M. Delgado III, M.D.

Page 159

15:15:56 1 (Delgado Deposition Exhibit 9  
15:15:59 2 marked.)  
15:15:59 3 BY MR. MORIARTY:  
15:16:01 4 Q. I've had this marked as Exhibit 9. It's  
15:16:03 5 a death certificate, correct?  
15:16:04 6 A. Uh-huh.  
15:16:05 7 Q. All right. May I see that?  
15:16:07 8 A. Yes.  
15:16:07 9 MR. WILLIAMSON: May I see it for  
15:16:08 10 two seconds?  
15:16:10 11 MR. MORIARTY: Could you give him my  
15:16:11 12 copy down there?  
15:16:12 13 MS. AHERN: Yeah. Here you go.  
15:16:14 14 MR. WILLIAMSON: I can't see the one  
15:16:15 15 you're showing the witness.  
15:16:17 16 MR. MORIARTY: You think it's  
15:16:18 17 different?  
15:16:18 18 MR. WILLIAMSON: No, if you tell me  
15:16:19 19 it's the same.  
15:16:20 20 BY MR. MORIARTY:  
15:16:21 21 Q. Okay. Date of death is what?  
15:16:23 22 A. September 28th, '08.  
15:16:25 23 Q. And is your signature on here?  
15:16:26 24 A. Yes.  
15:16:27 25 Q. Here, on line 27?



Reynolds M. Delgado III, M.D.

Page 160

15:16:28 1 A. Yes.

15:16:29 2 Q. What is the date that you signed it?

15:16:31 3 A. 9/30/08.

15:16:33 4 Q. And what were the two immediate cause  
15:16:38 5 and the sequentially listed conditions?

15:16:43 6 A. Congestive heart failure,  
15:16:47 7 cardiomyopathy.

15:16:47 8 Q. All right. And the congestive heart  
15:16:51 9 failure is months, and the cardiomyopathy is years;  
15:16:55 10 is that correct?

15:16:55 11 A. Yes.

15:16:55 12 Q. Have you undertaken any procedures to  
15:16:58 13 change this death certificate?

15:17:02 14 A. No.

15:17:02 15 Q. And that death certificate was executed  
15:17:17 16 five months after the recall of Digitek, correct?

15:17:23 17 A. Roughly, yes.

15:17:30 18 MR. MORIARTY: All right. Let's  
15:17:31 19 take a break. I'm going to collate all this mess  
15:17:34 20 and hopefully wrap this up, okay?

15:17:37 21 THE WITNESS: Thanks.

15:17:38 22 (Recess taken, 3:17 p.m. to  
15:31:21 23 3:31 p.m.)

15:31:22 24 BY MR. MORIARTY:

15:31:22 25 Q. Okay, Doctor. I'm going to try to wrap

Reynolds M. Delgado III, M.D.

Page 161

15:31:24 1 this up.

15:31:29 2 Why did Mrs. Vega still qualify for  
15:31:33 3 a heart transplant by the end of August 2008? And  
15:31:47 4 to put it another way, if you're confused by my  
15:31:51 5 question, is: Weren't there certain things that had  
15:31:56 6 happened to her by August of 2008 that would have  
15:31:59 7 made her not a candidate for heart transplant?

15:32:03 8 A. Candidacy for a heart-transplant thing  
15:32:07 9 is a very complicated, multi-disciplinary  
15:32:21 10 decision-making process that takes into account an  
15:32:24 11 entire board of people, some of which are  
15:32:27 12 physicians, some are not; and so there's no easy  
15:32:30 13 answer to that.

15:32:31 14 Q. Well, that's fine.

15:32:32 15 A. Obviously, we're dealing with limited  
15:32:34 16 resourcing, so with a limited resource, you can't  
15:32:37 17 have a single decision-maker. You have to make sure  
15:32:39 18 that there's no improprieties or biases and so on.  
15:32:43 19 So we have a board, and the board decides these  
15:32:45 20 things, not me personally.

15:32:47 21 Q. Okay. That's fine. And would the  
15:32:48 22 board, or a substantial part of the board, have  
15:32:50 23 reassessed the situation when a heart became  
15:32:54 24 available?

15:32:55 25 A. Absolutely.

Reynolds M. Delgado III, M.D.

Page 162

15:32:55 1 Q. Okay. All right. Of the -- you're  
15:33:04 2 probably aware there are dozens, if not hundreds, of  
15:33:07 3 articles about digoxin and digoxin toxicity,  
15:33:10 4 correct?

15:33:10 5 A. Yes.

15:33:10 6 Q. Well-documented topic in the medical  
15:33:13 7 literature?

15:33:14 8 A. Yes.

15:33:16 9 Q. And the only one you brought is this  
15:33:19 10 Exhibit 17, correct?

15:33:19 11 A. Right.

15:33:20 12 Q. Are there articles indicating that  
15:33:23 13 digoxin is not toxic at levels less than 2?

15:33:32 14 A. Not that I know of.

15:33:33 15 Q. All right.

15:33:34 16 A. The reason I only brought that is  
15:33:36 17 because that's the only one relevant. It doesn't  
15:33:39 18 have to do with what you're thinking of as digoxin  
15:33:41 19 toxicity.

15:33:44 20 Q. Okay.

15:33:44 21 A. You're thinking of a different syndrome.

15:33:44 22 (Delgado Deposition Exhibit 19  
15:33:44 23 marked.)

15:33:46 24 BY MR. MORIARTY:

15:33:46 25 Q. Okay. I have marked Exhibit 19. You

Reynolds M. Delgado III, M.D.

Page 163

15:33:51 1 see this?

15:33:52 2 A. Yes.

15:33:52 3 Q. This is a Lanoxin product label, okay?

15:33:57 4 A. Yes.

15:33:57 5 Q. And I'd like you to go to the

15:34:00 6 second-to-last page.

15:34:06 7 MR. WILLIAMSON: Do you have a copy

15:34:06 8 for me?

15:34:07 9 MR. MORIARTY: Actually, I don't.

15:34:08 10 I'm sorry.

15:34:09 11 MR. WILLIAMSON: That's okay.

15:34:10 12 MR. MORIARTY: You want to use my

15:34:11 13 highlighted one?

15:34:12 14 MR. WILLIAMSON: Well, yeah, let me

15:34:14 15 just get a copy made of it. Let's take a 30-second

15:34:18 16 break. It will only take me a second to make a

15:34:22 17 copy.

15:34:27 18 (Discussion off the record.)

15:34:51 19 MR. MORIARTY: Why don't I ask my

15:34:52 20 other two questions until he comes back with the

15:34:55 21 copy, and then I can ask you about that, to save

15:34:57 22 time, okay?

15:34:58 23 MR. WILLIAMSON: Yeah, because this

15:34:59 24 isn't one of the medical charts, so I can't just

15:35:03 25 follow along on my own copy of the medical chart.

Reynolds M. Delgado III, M.D.

Page 164

15:35:05 1 MR. MORIARTY: That's fine.

15:35:06 2 BY MR. MORIARTY:

15:35:08 3 Q. Doctor, let me go to something else, and

15:35:10 4 I'll come back to that, okay?

15:35:11 5 A. Yes, sir.

15:35:11 6 Q. I assume I'm being charged for the time

15:35:14 7 spent chatting with you today?

15:35:16 8 A. I don't -- I don't know, honestly. I

15:35:19 9 don't know how it works.

15:35:19 10 Q. Who handles that in your office?

15:35:22 11 A. I know I'm getting paid, if that's what

15:35:25 12 you're asking. Is that what you're asking?

15:35:28 13 Q. That was my question, if I'm unclear.

15:35:32 14 If you want to get paid, you've got to charge me,

15:35:35 15 right?

15:35:35 16 A. I don't know who I'm charging. I don't

15:35:36 17 know who's paying me.

15:35:39 18 Q. What do you expect to be paid for your

15:35:41 19 time here today, regardless of who pays it?

15:35:43 20 A. There's roughly a -- guidelines put

15:35:52 21 forth by the TMA that determines how we're paid for

15:35:55 22 doing work like this, and my office manager deals

15:35:58 23 with it.

15:35:58 24 Q. Okay. Do you know whether your office

15:36:01 25 manager has billed Mr. Williamson for any time

Reynolds M. Delgado III, M.D.

Page 165

15:36:06 1 you've spent talking to him before today?

15:36:08 2 A. No.

15:36:09 3 Q. No, you don't know --

15:36:10 4 A. No, he's not. No, he's not.

15:36:12 5 Q. Has Mr. Williamson indicated that he  
15:36:17 6 intends to retain you as an expert in this case?

15:36:19 7 A. No.

15:36:19 8 Q. All right. Now you can turn to  
15:36:23 9 Exhibit -- is it 19?

15:36:27 10 A. 19.

15:36:28 11 Q. All right. And, as I told you, I want  
15:36:30 12 you to go to the second-last page of the document.

15:36:36 13 MR. WILLIAMSON: The next-to-last  
15:36:37 14 page or two from the back?

15:36:39 15 MR. MORIARTY: Yes, sir.

15:36:40 16 MR. WILLIAMSON: Two from the back.

15:36:41 17 MR. MORIARTY: The penultimate page,  
15:36:44 18 yes, sir.

15:36:44 19 MR. WILLIAMSON: I don't know what  
15:36:45 20 "penultimate" means.

15:36:47 21 BY MR. MORIARTY:

15:36:48 22 Q. In the middle column, under the bigger  
15:36:51 23 heading of "Dosage and Administration," the second  
15:36:55 24 bold category is "Serum Digoxin Concentrations"; is  
15:36:58 25 that correct?

Reynolds M. Delgado III, M.D.

Page 166

15:36:58 1 A. Yes.

15:36:58 2 Q. All right. And you know what these are.

15:37:01 3 This is the package insert or the detailed patient  
15:37:05 4 labeling from the PDR regarding this particular  
15:37:08 5 drug, right?

15:37:08 6 A. Yes.

15:37:08 7 Q. Okay. The sixth line down, it says,  
15:37:18 8 "About two-thirds of adults considered adequately  
15:37:24 9 digitalized (without evidence of toxicity) have  
15:37:27 10 serum digoxin concentrations ranging from .8 to  
15:37:32 11 2.0 nanograms per milliliter."

15:37:38 12 Did I read that correctly?

15:37:40 13 A. Yes.

15:37:40 14 Q. Do you agree with that?

15:37:42 15 A. Yes.

15:37:42 16 Q. Next sentence, "However, digoxin may  
15:37:45 17 produce clinical benefits even at serum  
15:37:47 18 concentrations below this range."

15:37:52 19 Do you agree with that?

15:37:53 20 A. You would have to specify. This is all  
15:37:56 21 talking about a-fib, not heart failure.

15:38:01 22 Q. Why do you say that?

15:38:02 23 A. This is the basic premise of  
15:38:14 24 digitoxicity that's been around for, you know, many,  
15:38:17 25 many years, many decades, for a-fib management; and

Reynolds M. Delgado III, M.D.

Page 167

15:38:25 1 digitalization refers to digi loading.

15:38:30 2 Q. Is there some indication in this product  
15:38:32 3 label itself that this only has to do with a-fib  
15:38:35 4 patients?

15:38:37 5 A. The problem is that this data, the DIG  
15:38:44 6 trial and the Kirkwood Adams paper is not reflected  
15:38:48 7 in any of this. And that's a failing of this  
15:38:54 8 product insert to keep up with the current state of  
15:38:59 9 literature, which is actually a breach of FDA  
15:39:03 10 protocol; but, you know, there it is.

15:39:05 11 MS. AHERN: Objection,  
15:39:06 12 nonresponsive.

15:39:07 13 BY MR. MORIARTY:

15:39:08 14 Q. These are FDA-approved labels, are they  
15:39:10 15 not?

15:39:10 16 A. They're FDA-approved. They were  
15:39:12 17 FDA-approved. Part of the FDA approval process  
15:39:15 18 requires the corporations to keep abreast of changes  
15:39:20 19 in the literature and then advise the FDA of changes  
15:39:25 20 and update their labeling.

15:39:27 21 Q. Is it your opinion that GSK is in  
15:39:30 22 violation of some FDA provisions because this label  
15:39:33 23 is out of date?

15:39:35 24 A. Probably.

15:39:40 25 Q. It next says, "About two-thirds of adult



Reynolds M. Delgado III, M.D.

Page 168

15:39:48 1 patients with clinical toxicity have serum digoxin  
15:39:52 2 concentrations greater than 2.0 nanograms per  
15:39:57 3 milliliter."

15:40:05 4 Do you see that? It's the next  
15:40:05 5 sentence from what I just read.

15:40:12 6 A. Yes, I see that sentence.

15:40:13 7 Q. Okay. Do you agree with it?

15:40:14 8 A. Again, in reference to a-fib,  
15:40:22 9 digitalization, which is a term that goes back to  
15:40:25 10 the 18th Century.

15:40:30 11 Q. Okay. Down below, it says, "Rarely,  
15:40:35 12 there are patients who are unable to tolerate  
15:40:38 13 digoxin at serum concentrations below .8 nanograms  
15:40:41 14 per milliliter."

15:40:44 15 Do you see that?

15:40:45 16 A. Yes.

15:40:55 17 Q. Okay. "Consequently, the serum  
15:40:58 18 concentration of digoxin should always be  
15:41:02 19 interpreted in the overall clinical context, and an  
15:41:06 20 isolated measurement should not be used alone as the  
15:41:09 21 basis for increasing or decreasing the dose of the  
15:41:11 22 drug."

15:41:12 23 Do you see that?

15:41:12 24 A. Yes.

15:41:12 25 Q. Do you agree with that?

Reynolds M. Delgado III, M.D.

Page 169

15:41:14 1 A. I think that's a poor statement of the  
15:41:20 2 fact. Actually, the first sentence in that  
15:41:21 3 paragraph, "In general, the dose of digoxin should  
15:41:25 4 be determined by clinical grounds," that covers  
15:41:28 5 them, GSK; and is probably the best way to sum up  
15:41:32 6 the entire paragraph.

15:41:33 7 Q. And you agree with it?

15:41:34 8 A. Yes.

15:41:37 9 MR. MORIARTY: Okay. That's all I  
15:41:39 10 have. Thanks for your patience.

15:41:41 11 THE WITNESS: Thank you.

15:41:42 12 MR. MORIARTY: Ms. Ahern may have a  
15:41:43 13 few.

15:41:44 14 MR. WILLIAMSON: What number is  
15:41:45 15 that?

15:41:47 16 THE REPORTER: 19.

15:41:49 17 MR. WILLIAMSON: This is 19?

15:41:51 18 THE REPORTER: Yes, sir.

15:41:52 19 MR. WILLIAMSON: Thank you. That's  
15:42:04 20 the way you're marking exhibits, Delgado Exhibit 19?

15:42:04 21 MR. MORIARTY: That's what it says  
15:42:07 22 on the exhibit sticker, yeah. We decided not to go  
15:42:09 23 consecutive with Scottie because what we marked with  
15:42:11 24 him wasn't medical records.

15:42:13 25 MR. WILLIAMSON: I get it. It's all

Reynolds M. Delgado III, M.D.

Page 170

15:42:14 1 good. I just wanted to make sure I understood the  
15:42:16 2 system.

15:42:18 3 EXAMINATION

15:42:18 4 BY MS. AHERN:

15:42:19 5 Q. I will try and do this very quickly  
15:42:21 6 because I know you're tired and you probably have  
15:42:24 7 better things to do today. But there were a few  
15:42:26 8 things I wanted to follow up on just for my own  
15:42:29 9 understanding and a few more things I wanted to talk  
15:42:31 10 about.

15:42:31 11 First of all, you mentioned earlier  
15:42:32 12 that you don't like to order tests that you don't  
15:42:34 13 plan to act on, correct?

15:42:35 14 A. Yes.

15:42:36 15 Q. You said that it could be harmful to  
15:42:38 16 patients; is that correct?

15:42:39 17 A. Yes.

15:42:39 18 Q. Can you tell me why?

15:42:41 19 A. This is a medical student mistake, and  
15:42:45 20 it's something we train out of them, usually by  
15:42:52 21 residency or fellowship.

15:42:55 22 Basically, you don't do anything in  
15:42:57 23 medicine in which the outcome of that would not  
15:43:04 24 change your management of the patient in any way,  
15:43:07 25 because by making any move in medicine in which the

Reynolds M. Delgado III, M.D.

Page 171

15:43:13 1 outcome will not be changed, you have introduced the  
15:43:18 2 potential for harming the patient but have not  
15:43:22 3 introduced the potential for benefiting the patient.  
15:43:25 4 So you can only do harm by doing that.

15:43:28 5 Q. And when you say "you can only do harm,"  
15:43:29 6 is that because you might act on that result?

15:43:32 7 A. Yes, in an adverse way.

15:43:35 8 Q. Okay.

15:43:36 9 A. It goes back to Hippocrates, actually,  
15:43:40 10 the very first rule --

15:43:41 11 Q. Do no harm?

15:43:41 12 A. -- of the Hippocratic Oath. Yeah.

15:43:45 13 Q. Okay. And this is random, also, as I'm  
15:43:47 14 going back through my notes.

15:43:49 15 We were talking about in 2003, when  
15:43:54 16 Ms. Rivera-Vega was on .125 digoxin?

15:43:58 17 A. Yes.

15:43:58 18 Q. And she was switched at some point  
15:44:01 19 to .25, and you mentioned that you didn't really  
15:44:02 20 remember why she was switched to .25, but that .25  
15:44:05 21 would have been an appropriate dose; is that  
15:44:07 22 correct?

15:44:07 23 A. Yes.

15:44:07 24 Q. And why do you think the .25 would still  
15:44:10 25 have been an appropriate dose for her?

Reynolds M. Delgado III, M.D.

Page 172

15:44:11 1 A. It mainly had to do with her weight, her  
15:44:14 2 size. Around that time, she was roughly in the  
15:44:20 3 130-kilo range.

15:44:22 4 Q. Pounds? I'm sorry, I'm not very --

15:44:25 5 A. 270, 280.

15:44:27 6 Q. Okay. So is the reason keeping her at  
15:44:29 7 the lower dose, even though she would not  
15:44:31 8 necessarily have been adversely affected by the  
15:44:33 9 higher dose?

15:44:34 10 A. I don't know. In retrospect -- I don't  
15:44:41 11 know. I mean, at the higher -- either dose is  
15:44:43 12 appropriate in that patient population at that time,  
15:44:46 13 with the understanding of medicine at that time --

15:44:50 14 Q. All right.

15:44:50 15 A. -- which was pre this.

15:44:53 16 Q. Okay. And then later in the records,  
15:44:54 17 she also seems to have gone back and forth  
15:44:57 18 between .125 and .25 in 2007 and 2008?

15:44:59 19 A. Uh-huh.

15:45:00 20 Q. Is it still your opinion that either one  
15:45:01 21 of those doses was probably appropriate for her?

15:45:04 22 A. Yes.

15:45:04 23 Q. Okay. And I have a couple of questions  
15:45:07 24 about the article. I've only had a chance to skim  
15:45:10 25 it, but I thought it would be helpful. If you need

Reynolds M. Delgado III, M.D.

Page 173

15:45:13 1 a couple minutes just to quickly review it, I just  
15:45:15 2 wanted to ask you a few questions about it.

15:45:18 3 A. Sure. Go ahead.

15:45:19 4 Q. Okay. Can you tell me a little bit --  
15:45:23 5 you said that the article is what you rely on, to  
15:45:27 6 some extent, to say that digoxin might be able to  
15:45:30 7 cause heart failure? Am I quoting you correctly?

15:45:34 8 A. Probably -- if that's why I said, it  
15:45:36 9 wasn't my intent. The article explains how this  
15:45:42 10 whole case evolved or came about, and I think in a  
15:45:47 11 general way, that's the best way to put it.

15:45:49 12 Q. Okay. Is there anything that you can  
15:45:51 13 point to in the article of significance, that you  
15:45:55 14 feel is significant to your opinion?

15:45:57 15 A. Well, the whole article. I mean, it has  
15:46:01 16 to be taken in its totality, and that's what's done  
15:46:04 17 when it's peer-reviewed and published in the Journal  
15:46:07 18 of the American College of Cardiology.

15:46:11 19 Q. Can you tell me what the author's  
15:46:13 20 conclusions are?

15:46:14 21 A. Beneficial effect of digoxin on  
15:46:22 22 morbidity and no excess mortality in women at serum  
15:46:26 23 concentrations from .5 to .9, whereas serum  
15:46:30 24 concentrations greater than or equal to 1.2 seem  
15:46:33 25 harmful.

Reynolds M. Delgado III, M.D.

Page 174

15:46:34 1 Q. And did they mention harmful how? I  
15:46:37 2 mean, did they correlate that with a particular  
15:46:39 3 outcome?

15:46:39 4 A. Mortality.

15:46:40 5 Q. Mortality?

15:46:41 6 Did they talk about any particular  
15:46:45 7 etiologies of mortality?

15:46:48 8 A. The etiology in mortality in all these  
15:46:53 9 patients is initiated by heart failure.

15:47:01 10 Q. And do you remember --

15:47:04 11 (Interruption off the record.)

15:47:04 12 MR. WILLIAMSON: We need to take a  
15:47:05 13 break, because this is Dr. Delgado's.

15:47:08 14 MS. AHERN: All right.

15:47:11 15 (Discussion off the record.)

15:47:14 16 BY MS. AHERN:

15:47:15 17 Q. And this is a retrospective analysis of  
15:47:17 18 results from an earlier study; is that correct?

15:47:18 19 A. From the DIG trial, yes.

15:47:20 20 Q. Do you remember what the populations  
15:47:22 21 were, what the criteria for selecting patients for  
15:47:23 22 the DIG trial was?

15:47:30 23 A. The entry criteria for the DIG trial are  
15:47:35 24 obviously published in the New England Journal  
15:47:41 25 paper, to -- but for this trial, which is a

Reynolds M. Delgado III, M.D.

Page 175

15:47:42 1 different -- it's a subset of that population, the  
15:47:42 2 study population is described on page 2 in the entry  
15:47:47 3 criteria there as well.

15:47:49 4 Q. But those patients would have been  
15:47:51 5 selected from the earlier study, which had its own  
15:47:53 6 selection criteria; is that correct?

15:47:54 7 A. Yes.

15:47:55 8 Q. Do you remember how many cohorts existed  
15:47:57 9 in the first study?

15:47:59 10 A. No.

15:47:59 11 Q. Do you remember what the cohorts were?

15:48:01 12 A. No.

15:48:02 13 Q. Do you remember if there was a  
15:48:05 14 particular ejection fraction requirement?

15:48:08 15 A. The specifics of the early DIG trial are  
15:48:13 16 published. You can get those. You don't need to  
15:48:14 17 ask me.

15:48:15 18 Q. Are you saying that that would not be  
15:48:17 19 important for the interpretation of this study,  
15:48:18 20 which was based on the earlier study?

15:48:20 21 A. The interpretation of this study, which  
15:48:21 22 is based on the earlier study, is explained in this  
15:48:23 23 study.

15:48:24 24 Q. Okay. Can you explain to me your  
15:48:26 25 interpretation of the conclusion that you read a few



Reynolds M. Delgado III, M.D.

Page 176

15:48:27 1 minutes ago?

15:48:28 2 A. My interpretation of that?

15:48:36 3 Q. Yes, sir, as a clinician.

15:48:37 4 A. Let's see. "Digoxin is an effective  
15:48:45 5 treatment for heart failure in women with reduced  
15:48:48 6 ejection fractions when the drug is used at a low  
15:48:49 7 serum concentrations -- at low serum concentrations.  
15:48:54 8 A beneficial effect on morbidity, and no excess  
15:48:57 9 mortality was observed, serum concentrations of .5  
15:49:00 10 to .9."

15:49:05 11 The best place to look in trial, to  
15:49:10 12 sum it all up for you, is the hazard ratio plot on  
15:49:15 13 page 501. The left, lower left, plots it all out.

15:49:21 14 Q. Can you tell me what the hazard ratio --

15:49:25 15 A. Differentiates it.

15:49:27 16 Q. What is the hazard ratio? Can you just  
15:49:28 17 explain the term to me?

15:49:29 18 A. Oh, my God. 1.0 is the line of unity.  
15:49:35 19 Anything above that, increased mortality; anything  
15:49:37 20 below it, decreased.

15:49:39 21 Q. Okay. Is there a hazard ratio, then,  
15:49:42 22 for patients in this study who had dig levels above,  
15:49:46 23 what was it, 1.2, as compared to those that had dig  
15:49:51 24 levels below 1.2?

15:50:08 25 A. Okay. 0.5 to 0.9 in women predicted an

Reynolds M. Delgado III, M.D.

Page 177

15:50:20 1 HR for death of .8, 95% confidence interval with a  
15:50:23 2 p value of .0245. For death or hospital stay, for  
15:50:31 3 worsening heart failure, .073. In contrast, .12 --  
15:50:39 4 levels from .12 to .2 were associated with an HR for  
15:50:43 5 death for women of 1.33, 95% confidence interval is  
15:50:49 6 1.01, with a p value of .049 significant.

15:50:53 7 Q. Okay. So, in layman's terms, what is a  
15:50:55 8 hazard value of 1.33 mean?

15:50:58 9 A. The best way to look at this, in  
15:51:02 10 layman's terms, would actually be to look at the p  
15:51:04 11 value; and a significant p value is anything less  
15:51:07 12 than .05. That's a good, general term.

15:51:12 13 Q. Okay. And you're talking about the  
15:51:14 14 statistical probability here, the strength of the  
15:51:16 15 statistics behind this number?

15:51:17 16 A. Yes.

15:51:18 17 Q. Okay. But what does a hazard ratio of  
15:51:23 18 1.33 mean?

15:51:24 19 A. It's a statistical term that has a  
15:51:28 20 statistical definition that you would have to look  
15:51:32 21 up.

15:51:32 22 Q. Well, how does it apply to the patient  
15:51:34 23 populations? I mean, it's part of their conclusion  
15:51:37 24 here.

15:51:38 25 A. The best way for lay people to

Reynolds M. Delgado III, M.D.

Page 178

15:51:43 1 understand this is a general term which I can make,  
15:51:45 2 which is that if the p value is less than .05, then  
15:51:50 3 the result is statistically significant.

15:51:54 4 Q. Okay. So these results are  
15:51:56 5 statistically significant?

15:51:58 6 A. Yes.

15:51:58 7 Q. But what does 1.33 -- what does the  
15:52:01 8 hazard value mean, if you were to explain how that  
15:52:04 9 relates to the different patient populations, they  
15:52:07 10 find a hazard ratio of 1.33?

15:52:10 11 A. The hazard ratio is a complex  
15:52:16 12 statistical definition you'll have to go look up.

15:52:19 13 Q. My understanding is that hazard ratio --  
15:52:21 14 I mean, while statistics does play a role, the  
15:52:25 15 confidence interval is just telling you how much  
15:52:27 16 weight to give to the actual hazard ratio. But I'm  
15:52:31 17 just wondering what the hazard ratio -- the  
15:52:34 18 significance of the hazard ratio 1.33 means in this  
15:52:38 19 particular study. What does it -- how does that  
15:52:40 20 support their findings?

15:52:40 21 A. It's very simple. It's either  
15:52:43 22 statistically significant or it is not.

15:52:45 23 Q. And it is statistically significant, we  
15:52:48 24 agree?

15:52:49 25 A. So there's no other relevance beyond

Reynolds M. Delgado III, M.D.

Page 179

15:52:51 1 that.

15:52:52 2 Q. Okay. So you can't tell me anything  
15:52:54 3 beyond that. You can't tell me what this -- the  
15:52:57 4 hazard ratio means for this study?

15:53:00 5 A. If somebody had a textbook, or if you  
15:53:03 6 can look on Google, I can get you a definition. I  
15:53:06 7 can do that, if you'd like.

15:53:07 8 Q. Well, the hazard ratio, doesn't that  
15:53:09 9 tell you how much risk is associated with a  
15:53:12 10 particular event?

15:53:15 11 A. Is that your definition of it?

15:53:16 12 Q. I'm asking you.

15:53:17 13 A. Or should that be mine?

15:53:18 14 Q. I'm asking you.

15:53:19 15 A. If you want a definition of it, I will  
15:53:20 16 go to Google and get you a definition. Otherwise,  
15:53:23 17 do not ask me again.

15:53:24 18 MR. WILLIAMSON: That is  
15:53:26 19 repetitious.

15:53:28 20 THE WITNESS: Let's be simple about  
15:53:29 21 it.

15:53:29 22 BY MS. AHERN:

15:53:30 23 Q. Okay. So you're refusing to give me  
15:53:31 24 your definition of "hazard ratio"?

15:53:33 25 MR. WILLIAMSON: No, no, no, no.

Reynolds M. Delgado III, M.D.

Page 180

15:53:34 1 A. Absolutely not. I just --  
15:53:35 2 MR. WILLIAMSON: Stop. Stop. Stop.  
15:53:36 3 Stop. Stop.  
15:53:36 4 BY MS. AHERN:  
15:53:37 5 Q. I don't mean to make you angry. I'm  
15:53:39 6 just trying to understand.  
15:53:39 7 MR. WILLIAMSON: Stop. Stop. Stop.  
15:53:40 8 Don't answer.  
15:53:41 9 THE WITNESS: I'm not answering.  
15:53:43 10 MR. WILLIAMSON: Okay. You've asked  
15:53:43 11 him several times.  
15:53:44 12 BY MS. AHERN:  
15:53:44 13 Q. Okay. My point is that I understand --  
15:53:45 14 A. You don't understand anything.  
15:53:47 15 Q. -- that the hazard ratio is different  
15:53:47 16 from the 95% confidence level.  
15:53:51 17 A. You're so arrogant. You don't  
15:53:51 18 understand anything.  
15:53:55 19 Q. All right. We'll move on, then. Can  
15:53:57 20 you show me -- strike that.  
15:54:03 21 You mentioned that your belief that  
15:54:09 22 Mimi Rivera-Vega's condition and death was  
15:54:12 23 ultimately caused by digoxin was based in large part  
15:54:16 24 on this Kirkwood Adams article. Am I quoting you  
15:54:21 25 correctly?

Reynolds M. Delgado III, M.D.

Page 181

15:54:21 1 A. No.

15:54:21 2 Q. Okay. Can you explain to me, then, what  
15:54:22 3 your position is?

15:54:23 4 A. Her death was caused by a company that  
15:54:25 5 you represent, creating and marketing interstate  
15:54:29 6 pills that had the wrong dosage of medicine in them.  
15:54:35 7 Even we like to reduce things to simplicity at  
15:54:39 8 times.

15:54:39 9 Q. Okay. And your belief that Mimi  
15:54:44 10 Rivera-Vega -- we've already talked about this, but  
15:54:46 11 your belief that she got bad pills is based on your  
15:54:49 12 knowledge that there was a recall; is that correct?

15:54:50 13 A. It's based on the totality of evidence.

15:54:54 14 Q. There's no other --

15:54:57 15 A. The entire chart.

15:54:57 16 Q. -- differential diagnosis?

15:54:59 17 A. The entire chart.

15:54:59 18 Q. I understand that.

15:54:59 19 A. I've already answered that question.

15:55:00 20 Q. My next question is: In terms of  
15:55:06 21 differential diagnosis, when you look at this entire  
15:55:08 22 chart, are there any other possible explanations for  
15:55:10 23 Mimi Rivera-Vega's death, other than bad pills?

15:55:14 24 A. There are many possible explanations,  
15:55:18 25 but the correct one, in my mind, has already been

Reynolds M. Delgado III, M.D.

Page 182

15:55:22 1 stated.

15:55:22 2 Q. Okay.

15:55:23 3 A. No other reasons.

15:55:25 4 Q. Based on this article, it was published

15:55:27 5 in 2005, which apparently says that women who have

15:55:33 6 digoxin levels of 1.2 or higher are at an increased

15:55:36 7 risk of mortality, have you changed your treatment,

15:55:41 8 your practice -- your treatment practices at all,

15:55:44 9 based on the results of this study?

15:55:51 10 A. Based on the results of this study, in

15:55:57 11 general, lower doses are used in older patients,

15:56:02 12 particularly in women. And, again, as the package

15:56:07 13 insert there says, using your clinical judgment.

15:56:10 14 Q. Okay.

15:56:10 15 A. Not levels.

15:56:12 16 Q. And, I'm sorry if this is in there

15:56:14 17 already. I just wondered if you know. Do you know

15:56:16 18 whether or not the women who were taking the drug in

15:56:18 19 this study -- did they all receive the same dose;

15:56:21 20 and if so, what dose did they receive?

15:56:23 21 A. You have to look at the details in each

15:56:28 22 criteria of the study. I just don't know the

15:56:30 23 specifics.

15:56:32 24 Q. Okay.

15:56:35 25 A. There's some discussion there about

Reynolds M. Delgado III, M.D.

Page 183

15:56:36 1 steady-state and how that's achieved.

15:56:40 2 Q. Do you have any idea, hypothetically,  
15:56:42 3 about how many double doses an individual would have  
15:56:45 4 to take at steady-state to induce medically relevant  
15:56:50 5 results?

15:56:50 6 A. That question doesn't make -- doesn't  
15:56:54 7 make sense.

15:56:56 8 Q. Let's say you have a patient who's  
15:56:58 9 taking .125 milligrams of Digitek daily at  
15:57:03 10 steady-state and then takes a double dose of the  
15:57:05 11 medication, takes .25 --

15:57:07 12 A. Who's at steady-state?

15:57:08 13 Q. I'm sorry?

15:57:09 14 A. Who's at steady state?

15:57:11 15 Q. This hypothetical patient.

15:57:12 16 A. They're at steady-state?

15:57:13 17 Q. We have a patient who's been taking  
15:57:15 18 Digitek for a month and --

15:57:16 19 A. That's better way to put it.

15:57:17 20 Q. -- has reached steady-state.

15:57:20 21 A. Uh-huh.

15:57:20 22 Q. Has been taking .125. Hypothetically,  
15:57:24 23 with the patient who has normal renal function, how  
15:57:27 24 many double doses do you think that patient would  
15:57:30 25 have to have on consecutive days in order to see



Reynolds M. Delgado III, M.D.

Page 184

15:57:33 1 some sort of perturbation in the steady-state level

15:57:38 2 that results in medically significant consequences?

15:57:42 3 A. I already answered that question. We've  
15:57:44 4 talked about this before. We're rehashing old  
15:57:50 5 things.

15:57:51 6 Q. I don't remember asking you a  
15:57:52 7 hypothetical on that, but...

15:57:54 8 A. Yeah. I discussed it with him. He  
15:57:57 9 asked.

15:58:00 10 Q. He asked you how many -- how many double  
15:58:02 11 doses a person would have to take?

15:58:04 12 MR. MORIARTY: I didn't ask that as  
15:58:05 13 a hypothetical.

15:58:06 14 THE WITNESS: We've been through all  
15:58:07 15 that. We've been through all that. We've been  
15:58:08 16 through it multiple times. We don't need to rehash  
15:58:11 17 it.

15:58:11 18 MR. MORIARTY: I only asked if he  
15:58:12 19 had an opinion how many she took, not this  
15:58:14 20 hypothetical question.

15:58:16 21 THE WITNESS: Well, I don't answer  
15:58:18 22 hypothetical questions. I don't believe in them.

15:58:19 23 MS. AHERN: Okay.

15:58:22 24 BY MS. AHERN:

15:58:22 25 Q. Based on your reading of this article,

Reynolds M. Delgado III, M.D.

Page 185

15:58:24 1 this Kirkwood Adams article, would you now say that  
15:58:30 2 serum digoxin concentrations are relevant for  
15:58:32 3 treatment purposes?

15:58:35 4 A. I've always said they're irrelevant for  
15:58:39 5 treatment purposes.

15:58:40 6 Q. Irrelevant or relevant?

15:58:41 7 A. Irrelevant.

15:58:41 8 Q. Irrelevant?

15:58:42 9 A. I've explained that in great detail.

15:58:44 10 Q. Okay. Well, in this particular article,  
15:58:45 11 they indicate that serum digoxin concentrations of  
15:58:48 12 1.2 or higher in women might increase the risk of  
15:58:52 13 mortality. Would that change, then, how you treat  
15:58:54 14 patients? Would you then decide to monitor levels  
15:58:58 15 more closely?

15:58:58 16 A. That is why people like you shouldn't be  
15:59:01 17 trying to interpret articles like this. Because  
15:59:04 18 that's exactly what it doesn't say.

15:59:08 19 Q. Okay. I apologize that I don't  
15:59:09 20 understand. Could you explain to me the --

15:59:11 21 A. Well, I cannot teach you. I'm sorry.  
15:59:14 22 This is something that's very difficult for me to  
15:59:17 23 try to teach you. Cause and effect, try  
15:59:24 24 understanding that. Causality, just try  
15:59:31 25 understanding that little piece of it, and maybe

Reynolds M. Delgado III, M.D.

Page 186

15:59:33 1 you'll get the whole picture.

15:59:38 2 And the other thing I've answered  
15:59:40 3 already before is, this trial doesn't apply to one  
15:59:43 4 patient. It applies to a population. This is a  
15:59:47 5 tool that you use to make decisions, clinical  
15:59:50 6 decision-making, and that you use -- in this case,  
15:59:55 7 you use to discover the truth of this case.

16:00:01 8 It has nothing to do with getting  
16:00:03 9 levels. You know, it takes -- it takes medical  
16:00:06 10 students usually a couple years to get through that,  
16:00:11 11 and I don't expect to get through to you today.

16:00:15 12 Q. Okay. And one more thing I wasn't sure  
16:00:24 13 that I understood. You mentioned that this  
16:00:29 14 particular article, the Kirkwood Adams article,  
16:00:33 15 addressed a different syndrome than digoxin  
16:00:38 16 toxicity?

16:00:39 17 A. Uh-huh.

16:00:40 18 Q. Can you explain what you mean by  
16:00:41 19 "different syndrome"? Is there something other than  
16:00:45 20 digoxin toxicity that can be caused by digoxin?

16:00:48 21 A. Yes. Digoxin causes progressive  
16:00:52 22 worsening of heart failure, culminating in  
16:00:55 23 cardiogenic shock. It takes whatever reserve you  
16:00:57 24 have left, causes you to go over the -- I don't know  
16:01:03 25 how I put it before, over the --

Reynolds M. Delgado III, M.D.

Page 187

16:01:06 1 MR. MORIARTY: Cliff.

16:01:06 2 A. Cliff, yeah.

16:01:08 3 BY MS. AHERN:

16:01:08 4 Q. Cliff.

16:01:08 5 And is that talking about just this  
16:01:10 6 one patient or a population?

16:01:11 7 A. That's a population.

16:01:12 8 Q. Okay. So you would apply it both to a  
16:01:14 9 population and to --

16:01:15 10 A. And to this patient, yes.

16:01:16 11 Q. -- and to this patient?

16:01:18 12 MS. AHERN: Okay. I have no further  
16:01:19 13 questions.

16:01:20 14 MR. MORIARTY: Just a couple.

16:01:21 15 EXAMINATION

16:01:21 16 BY MR. MORIARTY:

16:01:21 17 Q. In these articles, what they're  
16:01:23 18 really -- particularly, article 17, that's the only  
16:01:26 19 one we have here, what they're trying to do is  
16:01:28 20 compare two populations, correct?

16:01:30 21 A. No.

16:01:30 22 Q. Well, they're taking a population of  
16:01:32 23 people whose serum digoxin concentration was .9 and  
16:01:37 24 below and statistically comparing it with outcomes  
16:01:41 25 of patients whose serum digoxin concentration was

Reynolds M. Delgado III, M.D.

Page 188

16:01:46 1 higher than 1.9, correct?

16:01:47 2 A. No. That is the other very difficult  
16:01:50 3 thing for lay people to understand, is the  
16:01:51 4 difference between a retrospective and a prospective  
16:01:53 5 study. What you're describing is a prospective  
16:01:57 6 study.

16:01:57 7 Q. Well, whether you call it a hazard ratio  
16:02:01 8 or whatever you want to call it, what is the  
16:02:03 9 increased level of risk to a female on digoxin with  
16:02:10 10 heart failure, if serum digoxin concentration is  
16:02:14 11 1.2, according to that article --

16:02:17 12 A. Increased?

16:02:17 13 Q. -- on a percentage basis?

16:02:19 14 A. There's no percentage. It's an  
16:02:20 15 increase.

16:02:21 16 Q. Okay. So we don't know -- we can't say  
16:02:23 17 how much the increase is?

16:02:26 18 A. No. You can say it's increased.

16:02:29 19 Q. All right. So you can't say that it is  
16:02:30 20 greater than 50%, for example?

16:02:33 21 A. You can say that it's statistically  
16:02:35 22 significantly increased.

16:02:39 23 Q. But not quantify the degree of increase?

16:02:42 24 A. Correct.

16:02:43 25 Q. Okay. Have you or anybody else done any

Reynolds M. Delgado III, M.D.

Page 189

16:02:48 1 study on patients in Texas Heart or at St. Luke's  
16:02:53 2 who may have been affected by Digitek? Any sort of  
16:02:59 3 gathering of numbers, retrospectively?

16:03:03 4 A. No. Like we talked about earlier, when  
16:03:08 5 patients came to clinic, we identified whether they  
16:03:12 6 were on it. We did some outreach when we found  
16:03:15 7 charts coming across our desks that showed the  
16:03:17 8 patients were on it. It was often very difficult to  
16:03:19 9 know unless it was written specifically in the  
16:03:21 10 chart. That's how our communication went back and  
16:03:25 11 forth.

16:03:25 12 Q. Okay. And Ms. Ahern asked you about  
16:03:28 13 this differential diagnosis; you said the most  
16:03:31 14 likely cause was this. What are these other  
16:03:33 15 possible causes of her going over the cliff in  
16:03:37 16 February of 2008?

16:03:43 17 A. There are not many other likely causes.

16:03:46 18 Q. What are the other possible causes in  
16:03:48 19 the differential?

16:03:51 20 A. I can't, offhand, think of any. Again,  
16:04:00 21 she was stable from '02 up to that point and  
16:04:03 22 actually losing weight, which is really the problem,  
16:04:09 23 which would have made her heart rate better,  
16:04:12 24 actually.

16:04:16 25 Q. I don't want to cut you off. Are you

Reynolds M. Delgado III, M.D.

Page 190

16:04:18 1 done with your answer?

16:04:20 2 A. Yeah.

16:04:20 3 Q. So as of today, you can't think of other  
16:04:22 4 possibilities that would have caused that event in  
16:04:26 5 February of 2008, other than defective digoxin  
16:04:37 6 tablets, correct?

16:04:37 7 A. Correct.

16:04:38 8 Q. But would the possibilities include  
16:04:42 9 whatever it was you diagnosed at the time?

16:04:45 10 A. I'm sorry, repeat that.

16:04:51 11 Q. Well, at the time, you and the team  
16:04:53 12 would have had to have diagnosed some cause of her  
16:05:00 13 falling off the cliff, if you will --

16:05:02 14 A. Uh-huh.

16:05:02 15 Q. -- correct?

16:05:03 16 A. No. No. The important thing was to  
16:05:06 17 diagnose that she was falling off the cliff.

16:05:08 18 Q. And treat that?

16:05:09 19 A. And treat that, yes.

16:05:10 20 Q. All right. But you never came to a  
16:05:11 21 diagnosis back then of why she fell off the cliff?

16:05:14 22 A. That's -- that wasn't relevant at the  
16:05:18 23 time. It was relevant to diagnose the problem,  
16:05:21 24 treat it. It then became, you know, eliminated  
16:05:27 25 later, retrospectively, what the cause was.

Reynolds M. Delgado III, M.D.

Page 191

16:05:30 1 MR. MORIARTY: Okay. That's all.  
16:05:31 2 Thanks.  
16:05:32 3 MS. AHERN: Done. Thank you.  
16:05:33 4 MR. WILLIAMSON: We'll reserve.  
16:05:34 5 (Recess taken, 4:05 p.m. to  
16:07:21 6 4:07 p.m.)  
16:07:21 7 MR. MORIARTY: Let's go back on the  
16:07:21 8 record.  
16:07:22 9 11 was a copy that Mr. Williamson  
16:07:25 10 gave me before the deposition. I used my copy;  
16:07:28 11 hence, it didn't come out of his chart.  
16:07:30 12 MR. WILLIAMSON: Right.  
16:07:32 13 MR. MORIARTY: 12, 13 --  
16:07:42 14 THE WITNESS: The key is --  
16:07:45 15 MR. MORIARTY: -- 15, 16 and 17 were  
16:07:48 16 in his chart, and I asked you if these were extra  
16:07:51 17 copies we could mark. And since they are not actual  
16:07:56 18 medical records but litigation-related, you said  
16:07:59 19 yes.  
16:08:00 20 THE WITNESS: No, that's not true.  
16:08:01 21 Everything that came in this chart with me is part  
16:08:03 22 of the parent's medical record.  
16:08:05 23 MR. MORIARTY: Right.  
16:08:05 24 THE WITNESS: I have to say that. I  
16:08:06 25 work with the FDA. I know all about their rules.



Reynolds M. Delgado III, M.D.

Page 192

16:08:09 1 I've done clinical trials. I know about all medical  
16:08:12 2 records.

16:08:12 3 MR. MORIARTY: Okay. It's part of  
16:08:13 4 the chart now, but these were things that were sent  
16:08:15 5 to you by Mr. Williamson on October 14th --

16:08:19 6 THE WITNESS: And it went straight  
16:08:20 7 into the chart in my office. That makes them part  
16:08:21 8 of the chart.

16:08:23 9 MR. MORIARTY: You deal with it the  
16:08:23 10 way you want. I asked if I could just pull them and  
16:08:26 11 mark them, and you all said yes.

16:08:28 12 MR. WILLIAMSON: I did.

16:08:28 13 THE WITNESS: No, I didn't say yes.

16:08:29 14 MR. WILLIAMSON: Dr. Delgado --

16:08:32 15 THE WITNESS: Jesus Christ. I'm  
16:08:34 16 responsible for this stuff. This is patient  
16:08:37 17 records.

16:08:37 18 MR. WILLIAMSON: I know. I'm going  
16:08:37 19 to bring the rest of this to you.

16:08:37 20 THE REPORTER: Off the record?

16:08:42 21 MR. WILLIAMSON: Yeah.

16:08:42 22 (Deposition concluded at 4:08 p.m.)

23 \* \* \* \* \*

24

25

Reynolds M. Delgado III, M.D.

Page 193

1 CHANGES AND SIGNATURE

2 REYNOLDS M. DELGADO III, M.D., F.A.C.C.

3 Monday, October 19, 2009

4

5 PAGE/LINE | CHANGE REASON

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Rennillo Deposition &amp; Discovery

Cleveland 216.523.1313 www.rennillo.com 888.391.3376 (Depo)

Reynolds M. Delgado III, M.D.

Page 194

1 I, REYNOLDS M. DELGADO III, M.D.,  
2 F.A.C.C., have read the foregoing deposition and  
3 hereby affix my signature that same is true and  
4 correct, except for the changes noted above.

5

6

REYNOLDS M. DELGADO III, M.D.,  
F.A.C.C.

7

8

9

10

11

COUNTY OF: \_\_\_\_\_ °

12

STATE OF: \_\_\_\_\_ °

13

14

Before me, \_\_\_\_\_,  
on this day personally appeared REYNOLDS M.  
15 DELGADO III, M.D., F.A.C.C., known to me (or proved  
to me under oath or through \_\_\_\_\_) to be the  
16 person whose name is subscribed to the foregoing  
instrument and acknowledged to me that they executed  
17 the same for the purposes and consideration therein  
expressed.

18

19

Given under my hand and seal of office this  
20 \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

21

22

23

NOTARY PUBLIC IN AND FOR  
THE STATE OF \_\_\_\_\_

24

25

My Commission Expires: \_\_\_\_\_

Reynolds M. Delgado III, M.D.

Page 195

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF WEST VIRGINIA  
3 CHARLESTON DIVISION

4 IN RE: DIGITEK PRODUCT LIABILITY LITIGATION ° MDL NO. 1968  
5 °  
6 °

7 SCOTTIE VEGA, Individually and as ° MDL NO.  
8 next friend of Christopher Vega, ° 2:09-CV-0768  
9 a minor and surviving natural °  
10 child of Mimi Rivera-Vega, °  
11 °

12 Plaintiff,

13 v.

14 ACTAVIS TOTOWA, LLC, et al., °  
15 °  
16 Defendants. °

17 REPORTER'S CERTIFICATION

18 ORAL DEPOSITION OF

19 REYNOLDS M. DELGADO III, M.D., F.A.C.C.

20 MONDAY, OCTOBER 19, 2009

21 I, Michael E. Miller, RDR, CRR, CLR and  
22 Notary Public in and for the State of Texas, do  
23 hereby certify that the facts as stated by me in the  
24 caption hereto are true;

25 That there came before me the  
aforementioned named person, who was by me duly  
sworn to testify the truth concerning the matters in  
controversy in this cause;

Reynolds M. Delgado III, M.D.

Page 196

1                   And that the examination was reduced to  
2     writing by computer transcription under my  
3     supervision; that the deposition is a true record of  
4     the testimony given by the witness.

5                   I further certify that I am neither  
6     attorney or counsel for, nor related to or employed  
7     by, any of the parties to the action in which this  
8     deposition is taken, and further that I am not a  
9     relative or employee of any attorney or counsel  
10    employed by the parties hereto, or financially  
11    interested in the action.

12                  Given under my hand and seal of office  
13    on October 27, 2009.

14

15

16

17

18

19

20

21

22

23

24

25

\_\_\_\_\_  
MICHAEL E. MILLER,  
NCRA Registered Diplomate Reporter  
NCRA Certified Realtime Reporter  
Certified LiveNote Reporter

Notary Public in and for  
The State of Texas  
My Commission Expires: 7/9/2012

Reynolds Delgado, M.D.

May 25, 2011

Page 197

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT ) MDL NO. 1968  
LIABILITY LITIGATION )  
THIS DOCUMENT RELATES )  
ONLY TO: )  
SCOTTIE VEGA, ) MDL NO. 2:09-CV-0768  
INDIVIDUALLY AND AS NEXT )  
FRIEND OF CHRISTOPHER )  
VEGA, A MINOR AND )  
SURVIVING NATURAL CHILD )  
OF MIMI RIVERA-VEGA, )  
PLAINTIFF )  
V. )  
ACTAVIS TOTOWA, L.L.C., )  
ET AL., )  
DEFENDANTS )

\* \* \* \* \*

ORAL DEPOSITION OF  
REYNOLDS M. DELGADO III, M.D., F.A.C.C.  
MAY 25, 2011

\* \* \* \* \*

ORAL DEPOSITION OF REYNOLDS M. DELGADO III, M.D.,  
F.A.C.C., produced as a witness at the instance of the  
DEFENDANTS ACTAVIS, INC., ACTAVIS ELIZABETH, L.L.C., AND  
ACTAVIS TOTOWA, L.L.C., and duly sworn, was taken in the  
above-styled and numbered cause on MAY 25, 2011, from  
1:38 p.m. to 8:10 p.m. before Teri Daigle, RPR, TCRR,  
CSR No. 4441, in and for the State of Texas, Louisiana  
CCR No. 23043, reported by machine shorthand, at the  
offices of Williamson & Rusnak, 4310 Yoakum Boulevard,  
Houston, Texas 77006, pursuant to the Federal Rules of  
Civil Procedure and the provisions stated on the record  
or attached hereto.

Reynolds Delgado, M.D.

May 25, 2011

Page 198

A P P E A R A N C E S

FOR THE PLAINTIFFS:

Cyndi Moss Rusnak

SBOT NO. 24007964

WILLIAMSON & RUSNAK

4310 Yoakum Boulevard

Houston, Texas 77006-5818

FOR THE DEFENDANTS ACTAVIS, INC.; ACTAVIS TOTOWA,  
L.L.C.; AND ACTAVIS ELIZABETH, L.L.C.:

Matthew P. Moriarty

TUCKER, ELLIS & WEST, L.L.P.

925 Euclid Avenue, Suite 1150

Cleveland, Ohio 44115-1414

FOR THE DEFENDANTS MYLAN PHARMACEUTICALS, INC.; MYLAN  
BERTEK PHARMACEUTICALS, INC.; AND UDL LABORATORIES,  
INC.:

Hunter K. Ahern

SBOT NO. 24050207

SHOOK, HARDY & BACON, L.L.P.

600 Travis Street, Suite 1600

Houston, Texas 77002-2911

## I N D E X

## PAGE

Appearances.....	198
Stipulations.....	205
REYNOLDS M. DELGADO III, M.D., F.A.C.C.	
Examination by Mr. Moriarty.....	205
Examination by Ms. Ahern.....	375
Reexamination by Mr. Moriarty.....	388
Signature and Changes.....	393
Reporter's Certificate.....	395

## E X H I B I T S

NUMBER	DESCRIPTION	PAGE
EXHIBIT 10-A	Curriculum Vitae of Reynolds M. Delgado III, M.D., F.A.C.C. (26 pages).....	207
EXHIBIT 20	History and Physical Examination, Mimi R. Vega dated 1-7-03 (3 pages).....	205
EXHIBIT 21	Discharge Summary, Mimi R. Vega dated 1-8-04 (2 pages).....	205
EXHIBIT 22	Discharge Summary, Mimi R. Vega dated 7-6-06 (2 pages).....	205
EXHIBIT 23	Discharge Summary, Mimi R. Vega dated 1-25-08 (1 page).....	205



Reynolds Delgado, M.D.

May 25, 2011

Page 200

## 1 E X H I B I T S

2	NUMBER	DESCRIPTION	PAGE
3	EXHIBIT 26	Report of Procedure, Mimi R. Vega dated	
4		10-18-07 (1 page).....	205
5	EXHIBIT 27	Operative/Procedure Note, Mimi R. Vega	
6		dated 10-19-07 (1 page).....	205
7	EXHIBIT 28	Psychosocial Evaluation, Transplant Service,	
8		Mimi R. Vega dated 10-23,24-07 (3 pages).....	205
9	EXHIBIT 29	GHC Patient Assessment, Mimi Vega dated	
10		10-17-07 (5 pages).....	205
11	EXHIBIT 30	Progress Note, Mimi R. Vega dated 11-17-07	
12		(1 page).....	205
13	EXHIBIT 31	Progress Note, Mimi R. Vega (2 pages).....	205
14	EXHIBIT 32	Heart Transplantation, Texas Heart Institute	
15		Heart Information Center (4 pages).....	205
16	EXHIBIT 33	Ventricular Assist Devices, Texas Heart	
17		Institute Heart Information Center (5 pages).	205
18	EXHIBIT 34	Use of a Continuous-Flow Device in Patients	
19		Awaiting Heart Transplantation, The New England	
20		Journal of Medicine (12 pages).....	205
21	EXHIBIT 35	Initial Clinical Experience With the Jarvik	
22		2000 Implantable Axial-Flow Left Ventricular	
23		Assist System (6 pages).....	205
24	EXHIBIT 36	Excerpt from 2003 PDR (2 pages).....	205

25

Reynolds Delgado, M.D.

May 25, 2011

Page 201

## E X H I B I T S

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
	NUMBER	DESCRIPTION																						
	EXHIBIT 37	ACC/AHA 2005 Guideline Update for the																						
		Diagnosis and Management of Chronic Heart																						
		Failure in the Adult-Summary Article: A																						
		Report of the American College of																						
		Cardiology/American Heart Association Task																						
		Force on Practice Guidelines, Circulation,																						
		Journal of the American Heart Association																						
		(32 pages).....																						
	EXHIBIT 38	EKG, Mimi R. Vega dated 1-22-08 (1 page).....																						
	EXHIBIT 39	Informed Consent, Mimi Vega dated 2-11-08																						
		(9 pages).....																						
	EXHIBIT 40	Jarvik 2000 Heart as a Bridge to Cardiac																						
		Transplantation-Pivotal Trial,																						
		ClinicalTrials.gov (3 pages).....																						
	EXHIBIT 41	Wal-Mart Pharmacy 10-4298 Medical Expenses																						
		Summary, Mimi Vega dated 9-9-09 (1 page).....																						
	EXHIBIT 42	Report of Procedure, Mimi Vega dated 2-5-08																						
		(1 page).....																						
	EXHIBIT 43	Letter from Whitson Ethridge, M.D., to																						
		Reynolds Delgado, M.D. dated 2-5-08 (1 page).205																						
	EXHIBIT 44	Report of Procedure, Mimi Vega dated 2-11-08																						
		(1 page).....																						

Reynolds Delgado, M.D.

May 25, 2011

Page 202

## 1 E X H I B I T S

2	NUMBER	DESCRIPTION	PAGE
3	EXHIBIT 45	Letter from Barry J. Zeluff, M.D. to	
4		Reynolds Delgado, M.D. dated 2-19-08	
5		(1 page).....	205
6	EXHIBIT 46	Report of Procedure, Mimi Vega dated 5-23-08	
7		(2 pages).....	205
8	EXHIBIT 47	Report of Procedure, Mimi Vega dated 5-17-08	
9		(2 pages).....	205
10	EXHIBIT 48	Report of Procedure, Mimi Vega dated 5-28-08	
11		(1 page).....	205
12	EXHIBIT 49	The Effect of Digoxin on Mortality and	
13		Morbidity in Patients with Heart Failure,	
14		The New England Journal of Medicine (9 pages)	205
15	EXHIBIT 49-A	Rationale, Design, Implementation, and	
16		Baseline Characteristics of Patients in the	
17		DIG Trial: A Large, Simple, Long-Term Trial	
18		to Evaluate the Effect of Digitalis on	
19		Mortality in Heart Failure (21 pages).....	205
20	EXHIBIT 50	Report of Reynolds Delgado, M.D., dated	
21		6-10-10 (22 pages).....	208
22	EXHIBIT 51	Notice of Deposition (3 pages).....	205
23	EXHIBIT 52	Heart Failure Pathogenesis and Treatment	
24		(13 pages).....	205
25			

Reynolds Delgado, M.D.

May 25, 2011

Page 203

## E X H I B I T S

1	2	NUMBER	DESCRIPTION	PAGE
3	EXHIBIT 53	Letter from Whitson Etheridge, M.D., to		
4		Reynolds Delgado, M.D. dated 11-5-07		
5		(1 page).....		205
6	EXHIBIT 54	Report of Procedure, Mimi R. Vega dated		
7		6-19-02 (1 page).....		205
8	EXHIBIT 55	Mechanical Circulatory Support for Advanced		
9		Heart Failure (5 pages).....		205
10	EXHIBIT 56	Long-Term Destination Therapy With the		
11		HeartMate XVE Left Ventricular Assist Device:		
12		Improved Outcomes Since the REMATCH Study		
13		(7 pages).....		205
14	EXHIBIT 57	Symptomatic Relief: Left Ventricular Assist		
15		Devices Versus Resynchronization Therapy		
16		(7 pages).....		205
17	EXHIBIT 58	Intravenous Milrinone in Treatment of		
18		Advanced Congestive Heart Failure (6 pages)..		205
19	EXHIBIT 59	The Use of Continuous Milrinone Therapy as		
20		Bridge to Transplant Is safe in patients With		
21		Short Waiting Times (5 pages).....		205
22	EXHIBIT 60	Progress Note, Mimi Vega dated 2-7-08		
23		(1 page).....		205
24	EXHIBIT 61	Medical Administration Records, Mimi Vega		
25		(82 pages).....		205

Reynolds Delgado, M.D.

May 25, 2011

Page 204

## E X H I B I T S

NUMBER	DESCRIPTION	PAGE
EXHIBIT 62	Digoxin in the Management of Cardiovascular Disorders, Circulation, Journal of the American Heart Association (7 pages).....	205
EXHIBIT 63	EKGs, Mimi Vega (8 pages).....	232

Reynolds Delgado, M.D.

May 25, 2011

Page 205

1 (EXHIBIT NOS. 20-23, 26-49A, AND 51-62  
2 PREVIOUSLY MARKED)

3 THE REPORTER: Would you state your  
4 agreements for the record, please.

5 MR. MORIARTY: We don't have any, do we?

6 MS. RUSNAK: We don't have any agreements  
7 other than taking it under the Federal Rules of Civil  
8 Procedure.

9 REYNOLDS M. DELGADO III, M.D., F.A.C.C.,  
10 having been first duly sworn, testified as follows:

11 EXAMINATION

12 BY MR. MORIARTY:

13 Q. Doctor, I know you've had your deposition taken  
14 before but just so you remember, if you don't understand  
15 my question, let me know and I'll make it clear to you.  
16 Okay?

17 A. Okay.

18 Q. I try to be as clear and scientifically  
19 accurate as I can, but I'm obviously not a cardiologist.  
20 So, if I mess up the terminology, just let me know; and  
21 I'll try to get at my question another way. Okay?

22 A. Okay.

23 Q. Anytime you need to take a break, let us know.  
24 We'll do that, okay --

25 A. Okay.

1 Q. -- as long as we're not right in the middle of  
2 a question and answer.

3 And if you need to look at a document, no  
4 matter what that document is, either dig for it or ask  
5 me and we will find it. Okay?

6 A. Okay.

7 Q. Now, this is Exhibit 51. This was a notice for  
8 this deposition. And in this I asked you to bring your  
9 office file regarding Mimi Rivera-Vega. Did you do  
10 that?

11 A. Yes.

12 Q. And did you bring a current C.V.?

13 A. Yes.

14 Q. Okay. May I have the C.V., please?

15 MS. RUSNAK: I may have that. Let me see.

16 A. (Tendering).

17 MR. MORIARTY: Now, Cyndi, I can either  
18 mark this 10-A, because 10 was his C.V. in the first  
19 depo; or I can mark it as No. 63. Do you care?

20 MS. RUSNAK: I do not.

21 MR. MORIARTY: Okay.

22 MS. RUSNAK: Whatever your preference is  
23 on that.

24 MR. MORIARTY: I'm going to mark it 10-A.

25 MS. RUSNAK: Okay.

1 (EXHIBIT NO. 10-A MARKED)

2 Q. (BY MR. MORIARTY) And, Dr. Delgado, I'm handing  
3 you Exhibit 10-A. Is that your current C.V.?

4 A. Yes.

5 Q. All right. Thank you.

6 And then Item 3 in the new notice, Exhibit 51,  
7 I asked you to bring all the material that you reviewed  
8 or relied upon to form your opinions in the case. Now,  
9 the first time we were here, we went through what you  
10 had reviewed to that point. So, I'm mostly interested  
11 in what additional information you may have reviewed.

12 A. That would be here, the letter from  
13 Dr. Frishman.

14 Q. Okay. And -- and just so we're clear, that's  
15 the defense expert report of Dr. Bill Frishman; correct?

16 A. Yes.

17 Q. Okay.

18 A. A letter from John Conti.

19 Q. Do you know Dr. Frishman?

20 A. No.

21 Q. You do know Dr. Conti, don't you?

22 A. No.

23 Q. Have you ever co-authored an article with  
24 Dr. Conti?

25 A. Not that I know of.



1 And then an expert report of Douglas Mann.

2 Q. You know Dr. Mann, don't you?

3 A. Yes.

4 Q. That goes on there.

5 A. The timeline, yeah.

6 Q. The timeline you're referring to was part of  
7 Dr. Mann's report; correct?

8 A. Correct. Yes.

9 Q. When Dr. Mann was here in Houston, did he have  
10 any supervisory role over your work at all?

11 A. No.

12 Q. You were just both members of the staff of  
13 St. Luke's and both members of Texas Heart?

14 A. Yes.

15 Q. Okay. All right. What else have you reviewed  
16 that's in addition to your earlier material?

17 A. My own deposition from October, '09.

18 Q. Okay.

19 A. And my letter --

20 Q. Okay.

21 A. -- from June, 2010.

22 (EXHIBIT NO. 50 MARKED)

23 Q. (BY MR. MORIARTY) All right. Your letter, when  
24 it came to me, had this "Plaintiff's A" on it. I've  
25 re-marked it as Exhibit 50. This is what you're talking

Reynolds Delgado, M.D.

May 25, 2011

Page 209

1 about --

2 A. Yes.

3 Q. -- your report of June 10, 2010?

4 A. Yes.

5 Q. Okay.

6 MR. MORIARTY: I don't know if anybody  
7 needs that, but I have extra copies.

8 Q. (BY MR. MORIARTY) Okay. What else?

9 A. That's it.

10 Q. All right. Did you review any additional  
11 material from FDA?

12 A. No.

13 Q. Did you review Craig Frost's deposition which,  
14 I believe, was taken after yours?

15 A. No.

16 Q. Did you review any purchasing records that were  
17 appended as exhibits to Craig Frost's deposition?

18 A. No.

19 Q. Have you undertaken any investigations of how  
20 many patients, for example, at St. Luke's or under the  
21 umbrella of Texas Heart were taking Digitek in 2008?

22 A. No.

23 Q. Have you -- there's typically a protocol for  
24 how you amend or change medical records. Have you  
25 initiated any protocol to change medical records of

1 yours related to Mimi Rivera-Vega?

2 A. No.

3 Q. Do you know -- do you recognize the distinction  
4 between possibility and probability?

5 A. I guess it would depend on the context.

6 Q. Okay. Well, at Page 1 of Exhibit 50, which is  
7 your letter report, you say that (Reading): The  
8 opinions here are based on my review of the materials,  
9 et cetera.

10 And up further, it says (Reading): All my  
11 opinions are expressed to a reasonable degree of medical  
12 probability.

13 Do you see that?

14 A. Yes.

15 Q. What do you mean by medical -- "reasonable  
16 degree of medical probability"?

17 A. The opinions are expressed in a way that is  
18 probable in a medical sense.

19 Q. Okay. Are you done with your answer?

20 A. Yes.

21 Q. From my past experience in this field and  
22 knowing what the law is in certain states, typically  
23 some courts and people say that probability is more  
24 likely than not; in other words, greater than 50 percent  
25 chance of something occurring. Do you agree with that?

1 A. It depends on the context.

2 Q. How would it be different in a different  
3 context?

4 A. If, for example, there was a qualifier just  
5 before the word "probability"; for example, high  
6 probability or low probability. And in medical  
7 terminology, such qualifiers are used.

8 Q. Okay. Well, would low probability, under those  
9 circumstances, be like 50 to 60 percent; or have you  
10 seen it -- low probability used in terms of something  
11 that's less than 50/50?

12 A. Actually, the way we use it, it is based on  
13 clinical identifiers. For example, low probability of  
14 active coronary disease being based on patients having  
15 certain clinical aspects to their case, that would put  
16 them at a low probability of having coronary disease;  
17 and such people then would not undergo heart  
18 catheterization.

19 Q. Okay. Well, that's a very good example of a  
20 discrete medical situation. But getting back to your  
21 report, Exhibit 50, we're talking about a medical/legal  
22 context. So, can we agree that probability is more  
23 likely than not, in general? And we'll parse it out  
24 later more specifically if we have to.

25 A. In a medical/legal sense.

1 Q. Okay. So, possibility, would you agree, would  
2 be sort of that 50/50 or less? It's more speculative;  
3 is that true?

4 A. Again, it depends on the context.

5 Q. So, if somebody said, for example -- let me  
6 withdraw that.

7 At some point today -- I might as well ask you  
8 this question now to give you an example: Do you  
9 remember when the first time was that you talked with  
10 Mimi Rivera-Vega about heart transplantation?

11 A. No.

12 Q. All right. There is a transplant nurse's note  
13 in October of 2007 which makes reference to Mimi telling  
14 that nurse that she had discussed transplant with  
15 somebody as early as the year 2000. Okay? I want you  
16 to assume that's true.

17 A. Okay.

18 Q. Would you then say it's possible that you or a  
19 member of your staff talked to her as early as 2002, to  
20 be fair to you because you didn't see her in 2000, that  
21 you or your staff spoke with her as early as 2002 about  
22 a heart transplant?

23 A. It's possible.

24 Q. Okay. So, this context, we're using  
25 possibility as you don't remember and, so, there is some

Reynolds Delgado, M.D.

May 25, 2011

Page 213

1 chance, but you don't know what that chance may be;  
2 correct?

3 A. Correct.

4 Q. If I were to then go on and say to you, "Is it  
5 probable that you were discussing heart transplant with  
6 Mimi from the time you first started seeing her in  
7 2002," is that probable or not?

8 A. I don't know.

9 Q. All right. Okay. Do you have any training in  
10 pharmaceutical quality assurance?

11 A. No.

12 Q. Pharmaceutical manufacturing?

13 A. No.

14 Q. Pharmaceutical distribution?

15 A. No.

16 Q. What about pharmacovigilance?

17 A. No.

18 Q. If I remember correctly, you have not actually  
19 worked as an employee of a pharmaceutical company; is  
20 that correct?

21 A. Correct.

22 Q. Before -- well, I'm sorry. Let me take a step  
23 back.

24 Have you ever reviewed an FDA Form 483?

25 A. I don't remember.

1 Q. Before this litigation, had you ever reviewed  
2 an FDA warning letter?

3 A. Yes.

4 Q. Okay. How many times before this litigation  
5 had you ever read an FDA warning letter?

6 A. Three or four.

7 Q. And what were those warning letters about? I'm  
8 sorry. I withdraw that question.

9 I know you've been an expert in other  
10 pharmaceutical or device pieces of litigation,  
11 specifically Gadolinium. Other than for purposes of the  
12 Gadolinium litigation or the Digitek litigation, have  
13 you ever reviewed an FDA warning letter?

14 A. Yes.

15 Q. Okay. In what context did you review a warning  
16 letter?

17 A. As part of training, we -- we are given those  
18 as examples as part of the training.

19 Q. Do you remember -- training for what, first of  
20 all?

21 A. To get certified to do clinical research.

22 Q. All right. So, this would have been during  
23 your fellowship?

24 A. No. It's got to be repeated every three years,  
25 I believe.

Reynolds Delgado, M.D.

May 25, 2011

Page 215

1 Q. All right.

2 A. I just finished relative -- last year I did  
3 one.

4 Q. Okay. Do you know anything about the legal  
5 ramifications of a warning letter?

6 A. No.

7 Q. Do you know in the pharmaceutical business what  
8 remediation of a warning letter is or remediation of a  
9 483?

10 A. No.

11 Q. Now, in this case there were -- the plaintiffs  
12 hired some pharmaceutical experts, quality people,  
13 manufacturing people, pharmacovigilance people, things  
14 of that nature. I'm going to ask you if you recognize  
15 these names and if you've read any of their material.  
16 One is named David Bliesner, B L I E S N E R.

17 A. Don't know.

18 Q. Haven't read his report or his deposition?

19 A. No.

20 Q. I apologize to Mr. Kenny, but I can't remember  
21 his first name. Mr. Kenny, he's from New Jersey.

22 MS. RUSNAK: Mark.

23 Q. (BY MR. MORIARTY) Mark. Have you read his  
24 deposition or seen his report?

25 A. No.



1 Q. What about Dr. Frank, pharmacovigilance expert  
2 from, I believe, Philadelphia, have you seen her report  
3 or read her deposition?

4 A. No.

5 Q. There was a Russell Somma, manufacturing  
6 expert, I believe, also from New Jersey. Have you seen  
7 his report or his deposition?

8 A. No.

9 Q. Have you read any batch records from the  
10 manufacturer Digitek?

11 A. I don't know what that is.

12 Q. Okay. When a pharmaceutical company blends and  
13 compresses a batch of tablets, for example, they have a  
14 record of that. They call it a batch record. Have you  
15 read any of those --

16 A. No.

17 Q. -- regarding Digitek?

18 And FDA and some other -- and some private  
19 companies have tested Digitek over the years at various  
20 times. Have you read any of the independent third-party  
21 testing of Digitek?

22 A. No.

23 Q. We marked in your first deposition an Exhibit  
24 No. 14. It was a -- and I'm sorry. I only brought my  
25 set of these.

1 MS. RUSNAK: I've got mine.

2 Q. (BY MR. MORIARTY) That is the FDA-approved  
3 press release for the Digitek recall. You've seen that  
4 before, have you not?

5 A. Yes.

6 Q. And in here --

7 MR. MORIARTY: I'm sorry. Cyndi, if you  
8 want to share yours with him...

9 Q. (BY MR. MORIARTY) Let me find where I have  
10 to -- okay. Right here in this paragraph where I'm  
11 pointing -- see where I'm pointing?

12 A. Yes.

13 Q. It says (Reading): The voluntary all-lot  
14 recall is due to the possibility that tablets with  
15 double the appropriate thickness may have been  
16 commercially released. These tablets may contain twice  
17 the approved level of active ingredient than -- should  
18 be "is" appropriate, but it says "than" appropriate.

19 Do you see that?

20 A. Yes.

21 Q. Okay. Do you have any information from any  
22 source that indicates to you that the Digitek recall was  
23 about some subject other than what was in the  
24 FDA-approved press release?

25 A. I don't understand the question.

1 Q. Sure.

2 Actavis drafted the press release. FDA  
3 generally has to approve those before they go out.  
4 Okay?

5 A. Okay.

6 Q. It states in there in what I've read what the  
7 purpose of the recall was or what initiated the recall.  
8 My question to you is: Do you have information from any  
9 other source to indicate that the recall was about  
10 something other than is contained in that press release?

11 MS. RUSNAK: Objection, form.

12 A. The answer is no.

13 Q. (BY MR. MORIARTY) Okay. Have you ever  
14 personally seen a Digitek tablet that was thicker than  
15 its FDA-approved specifications?

16 A. No.

17 Q. Have you ever seen a scientific -- I'm sorry.  
18 Let me withdraw that.

19 Have you ever seen a report of one?

20 A. No.

21 Q. Okay. You looked puzzled. So, let me follow  
22 up and make sure we're on the same page.

23 For example, a pharmacist might issue a report  
24 that you have seen saying, "Hey, I've got this Digitek  
25 tablet here, and it appears outside its specifications"

1 or "I measured it with a micrometer, and it's outside  
2 its specifications for thickness." Have you ever seen  
3 such a report?

4 A. No.

5 Q. Have you ever seen a report of a Digitek tablet  
6 that was tested by a laboratory to have been outside of  
7 its FDA-approved specifications for digoxin content?

8 A. No.

9 Q. Do you have any opinion to a reasonable degree  
10 of probability how many out-of-specification tablets  
11 Actavis actually manufactured?

12 A. No.

13 Q. Do you have any opinion to a probability of how  
14 many -- if they made any -- how many of them were  
15 shipped out of the plant to distributors and  
16 pharmacists?

17 A. No.

18 Q. Do you have any opinion to a reasonable degree  
19 of probability as to how many out-of-specification  
20 Digitek tablets Mimi Rivera ever received in any of her  
21 outpatient prescriptions?

22 A. I don't know.

23 Q. Before you -- we know that this lawsuit, Mimi  
24 Rivera-Vega's specific lawsuit -- I believe it was filed  
25 in 2009. I could look it up for specific dates if I

1 need to. Do you know whether the Vega family's  
2 lawyers -- Cyndi, Jimmy, Shelly, any of them -- spoke  
3 with you before the lawsuit was filed?

4 A. No.

5 Q. You don't know?

6 A. No, they did not.

7 Q. Okay. Do you remember the first time  
8 approximately when you spoke with any of the lawyers for  
9 Mimi's family?

10 A. Regarding her case?

11 Q. Yes.

12 A. I don't remember.

13 Q. Do you know whether before you -- before you  
14 ever spoke with Mimi's family's lawyers about this  
15 lawsuit whether you had expressed in writing to anyone  
16 the type of opinions about her cause of death that you  
17 have expressed in Exhibit 50?

18 A. No.

19 Q. Did you express opinions like those in Exhibit  
20 50 to anyone orally before you spoke with her lawyers --  
21 her family's lawyers, I should say?

22 A. Not that I know of.

23 Q. Before you were contacted -- or before you  
24 discussed this case with Mimi's family's lawyers, did  
25 you ever make any inquiry to the pharmacists at

1 St. Luke's, any pharmacists affiliated with Texas Heart,  
2 anyone like that regarding Digitek tablets or her  
3 prescriptions?

4 A. No.

5 Q. Now, in your first deposition, there was an  
6 exhibit marked No. 12. It was a warning letter from FDA  
7 to my client in August of 2006. Okay? You see that?

8 A. Yes.

9 Q. I'm not going to ask you any details about it;  
10 but you're welcome to refer to it, if need be. The  
11 thrust of that warning letter has to do with adverse  
12 event reporting which are pharmacovigilance issues. Do  
13 you remember that?

14 A. I don't remember offhand, but it appears that  
15 that's accurate.

16 Q. Okay. Do you know anything about whether  
17 Actavis remediated the points raised by the FDA in that  
18 warning letter?

19 A. I don't understand the question, specifically  
20 "remediated."

21 Q. Yeah. Well, I asked you about this before.  
22 It's -- remediation is, in essence, the pharmaceutical  
23 company's response, both in writing and in action, to  
24 take care of the problems that the FDA is addressing.  
25 That's my understanding of "remediation."

Reynolds Delgado, M.D.

May 25, 2011

Page 222

1 A. Okay.

2 Q. So, assuming I'm correct, do you have any  
3 knowledge of the degree to which Actavis remediated the  
4 FDA's concerns in that warning letter, Exhibit 12?

5 A. No.

6 Q. Regarding the impact of that and the degree to  
7 which those problems were taken care of by Actavis,  
8 would you defer to the plaintiffs' pharmacovigilance  
9 expert, Dr. Frank?

10 A. Yes.

11 Q. Okay. This one, Exhibit 13, is a revised  
12 warning letter dated February 1st, 2007. Okay? The  
13 only mention of Digitek is at Page 5 regarding something  
14 known as a cleaning validation study. Do you know what  
15 cleaning validation studies are in the pharmaceutical  
16 manufacturing or quality process?

17 A. No.

18 Q. The plaintiffs have a manufacturing expert,  
19 Russell Somma. And I think Mr. Bliesner and Mr. Kenny  
20 probably commented on this, also. Would you defer to  
21 them regarding the discussion of the significance of  
22 Exhibit 13?

23 A. Yes.

24 Q. Okay. Do you know whether either Exhibit 13 or  
25 12 specifically say that Actavis manufactured and

Reynolds Delgado, M.D.

May 25, 2011

Page 223

1 distributed Digitek that was outside of its FDA-approved  
2 specifications?

3 A. No, I don't know. I'm sorry.

4 Q. Do you want to review them now to see?

5 A. Sure.

6 Q. I can assure you it's not in there, but...

7 A. (Witness reviewing document).

8 Q. So, you've finished looking through No. 13.

9 Does it say anything in there about Actavis having  
10 actually manufactured and distributed  
11 out-of-specification tablets?

12 A. It doesn't specifically mention Digitek.

13 Q. Okay.

14 A. (Witness reviewing document).

15 Q. Okay. You've had a chance to look at No. 12.

16 Does it say anything in Exhibit 12 about Actavis having  
17 manufactured and distributed out-of-specification  
18 Digitek?

19 A. It mentions digoxin, not -- not the other name,  
20 Digitek.

21 Q. But the only reference to digoxin has to do  
22 with that cleaning validation study at Page 5; correct?

23 A. No, I don't believe so. If I could see it  
24 again, I'll point it out.

25 Q. Did I give you the right one?



1 A. No.

2 Q. Sorry.

3 And, so, you are now looking at 12 again?

4 A. Correct.

5 Q. Okay.

6 A. Page 2, No. 1 (Reading): Failure to submit to  
7 the FDA ADE reports as required by 21 CFR (sic), blah,  
8 blah, blah.

9 Q. Okay.

10 A. (Reading): Specifically, there were six  
11 potentially serious and unexpected adverse drug events  
12 dating back to 1999 for products, such as digoxin.

13 Q. All right. So, No. 12 is the one about  
14 pharmacovigilance. And it refers to digoxin; correct?

15 A. Yes.

16 Q. Okay. But it doesn't -- it just refers to  
17 adverse event reports. It doesn't say anything about  
18 having manufactured or distributed out-of-specification  
19 product?

20 A. Not specifically.

21 Q. Okay. Now, at your first deposition, I marked  
22 an exhibit -- I believe it was 14 -- and there was some  
23 question at the time because we had printed it -- I'm  
24 sorry. It was 18. We had printed it oddly. This time  
25 I printed it off the actual FDA's website. It's the --

1       been marked as Exhibit 38 in the MDL, and it's called  
2       "Facts and Myths about Generic Drugs." I would like you  
3       to turn to Page 2, please.

4               The first myth -- full myth on that page in  
5       bold says (Reading): There are quality problems with  
6       generic drug manufacturing.

7               Do you see that?

8           A.    Yes.

9           Q.    Okay. And then it says (Reading): A recent  
10       recall of generic digoxin (called Digitek) shows that  
11       generic drugs put patients at risk.

12               Do you see that?

13          A.    Yes.

14          Q.    And then it goes on to "Fact," and then it has  
15       five bullet points. Do you see where I'm talking about?

16          A.    Yes.

17          Q.    Let's go to the fourth bullet point. The  
18       second sentence says (Reading): In our best judgment,  
19       given the very small number of defective tablets that  
20       may have reached the market and the lack of reported  
21       adverse events before the recall, harm to patients was  
22       very unlikely.

23               First of all, did I read that correctly?

24          A.    Yes.

25          Q.    Do you have any reason to disagree with the FDA

1 on this statement from its website?

2 A. No.

3 Q. Can I have that back, please?

4 MS. AHERN: What are you looking for?

5 MR. MORIARTY: I just need to keep these  
6 straight. He can have it if he wants it.

7 Q. (BY MR. MORIARTY) There is a man named Craig  
8 Frost who, I believe, is the pharmacy manager at  
9 St. Luke's Hospital. At least that was his title when  
10 he was deposed in 2009 or '10. Do you know him?

11 A. No.

12 Q. Are you on any committees that have oversight  
13 for the pharmacy, such as a PNT committee or anything  
14 like that?

15 A. No.

16 Q. Would Mr. Frost probably be in a better  
17 position to interpret the records of the pharmacy  
18 department regarding the purchase and distribution  
19 within the hospital? Would he be in a better position  
20 than you to interpret those records?

21 A. Yes.

22 Q. Now, if you suspect a patient of yours of  
23 having taken an excess of a medication, whether  
24 intentionally or accidentally, do you have a method for  
25 investigating that?

1 A. Not a one-size-fits-all, no.

2 Q. Okay. Well, let's see if we can get some of  
3 the parameters, depending on what the circumstance may  
4 be. First of all, if the patient is alive, you could  
5 take a history -- you know, did you take your  
6 medications today, did you take the right amount, things  
7 of that nature?

8 A. Yes.

9 Q. That would be one step in the process; correct?

10 A. Yes.

11 Q. You could look for clinical signs and symptoms  
12 of an excess dose, could you not?

13 A. Yes.

14 Q. Some drugs are amenable to detection in blood  
15 or serum or urine through laboratory testing, aren't  
16 they?

17 A. Yes.

18 Q. So, you could, if appropriate, check whatever  
19 labs were there and available regarding looking for that  
20 drug; correct?

21 A. Yes.

22 Q. Some drug overdoses or excesses also have  
23 ancillary signs or symptoms that might be detected on  
24 other tests. For example, an EKG may show typical  
25 patterns of digoxin excess or diltiazem excess or

Reynolds Delgado, M.D.

May 25, 2011

Page 228

1 something like that; is that true?

2 A. Yes.

3 Q. And then certainly if there was some of the  
4 drug available, whether it was IV, IM, or oral, it could  
5 be tested -- is that correct -- to see if it was what it  
6 was purported to be?

7 A. Yes.

8 Q. So, for example, in -- some of your patients  
9 presumably take heparin from time to time?

10 A. Yes.

11 Q. There was in the last few years a big heparin  
12 recall because there was some contamination in some  
13 Chinese heparin plants or something like that. Those  
14 bags could be tested; is that right?

15 A. Yes.

16 Q. Okay. So, in Mimi Rivera-Vega's case, in your  
17 opinion, to a probability, did she have, in January of  
18 2008 -- January 22nd, 23rd to be precise -- did she have  
19 clinical signs or symptoms of having taken an excess of  
20 digoxin?

21 A. I don't remember.

22 Q. Are you -- are you done, or are you --

23 A. Yes.

24 Q. -- trying to remember?

25 Okay. Doctor, I'm not sure -- I have a binder

1 here with some medical records in it. I'm not sure that  
2 this is the complete handwritten history and physical,  
3 but I'd like you to take a look at these two pages here.  
4 And while I look for something else, tell me if that  
5 helps you answer my question about whether she had  
6 clinical signs or symptoms of digoxin toxicity or  
7 digoxin excess when she was admitted January -- she was  
8 admitted late on the 22nd, very close to midnight --  
9 22nd, 23rd.

10 A. (Witness reviewing document).

11 Q. And for fairness, Doctor, before you even  
12 answer my question, here is a typed discharge summary.  
13 Some of the information may have been carried over from  
14 an admission H&P. So, if you want to look at Exhibit 23  
15 and see if that helps you answer my question.

16 A. Okay.

17 Q. So, as a reminder, my question is: Do you have  
18 an opinion, to a reasonable degree of probability, as to  
19 whether or not she had clinical signs or symptoms of  
20 digoxin excess when she was admitted to the hospital  
21 January 22-23, 2008?

22 A. Yes.

23 Q. All right. And what were they?

24 A. A worsening of the heart failure with volume  
25 overload and nonsustained ventricular tachycardia, which

1 could have been a sign of toxicity.

2 Q. Okay. Are you done with your answer?

3 A. Yes.

4 Q. Now, let me just address the v-tach for a  
5 moment. Exhibit 38 is the EKG that was given to her on  
6 admission about eight minutes to midnight, January 22,  
7 2008. First of all, there is a computer interpretation  
8 on here, is there not?

9 A. Yes.

10 Q. Does it say anything about the digitalis effect  
11 in the computerized read of this?

12 A. No.

13 Q. Okay. Now, I know you don't use the computer  
14 reads in your clinical practice very much. Am I correct  
15 about that?

16 A. Correct.

17 Q. When you look at this EKG, if you were to  
18 interpret it, would you say that it has the classic  
19 digitalis effect?

20 A. It's not possible to do that.

21 Q. Why?

22 A. The underlying left bundle branch block.

23 Q. Obscures any ability to say that?

24 A. Correct.

25 Q. And left bundle branch block is a conduction

1 abnormality; is that correct?

2 A. Yes.

3 Q. So, so far as, I think you said, sustained  
4 (sic) v-tach, had she ever had that before this  
5 admission?

6 A. I'm sorry. I think it's nonsustained.

7 Q. I'm sorry. Well --

8 A. Nonsustained.

9 Q. All right. Had she ever had ventricular  
10 tachycardia before -- before this admission?

11 A. I don't remember.

12 Q. Would it make any difference to you if, in  
13 fact, on prior EKGs, she did, in fact, have ventricular  
14 tachycardia? That's a bad question.

15 A. I'm sorry. Yeah. The question --

16 Q. I'm going to withdraw it.

17 You -- I asked you what the signs and symptoms  
18 of digoxin excess were as of the time of this admission;  
19 and among them, you mentioned ventricular tachycardia.  
20 Okay. If she had had ventricular tachycardia in  
21 previous admissions where there was no question of  
22 digoxin excess, would you still agree that the  
23 ventricular tachycardia here is a sign or symptom of  
24 digoxin excess?

25 A. I can't accurately answer that question.



Reynolds Delgado, M.D.

May 25, 2011

Page 232

1 Q. Why not?

2 A. Because the original premise you put forth was  
3 false.

4 Q. Which original premise?

5 THE WITNESS: Could you play it back?

6 Q. (BY MR. MORIARTY) She probably can't.

7 But what are you telling me was false about my  
8 assumption or my question?

9 A. No, your statement. It wasn't part of the  
10 question.

11 Q. Which --

12 A. Your original statement was incorrect.

13 Q. Which statement?

14 A. The statement that preceded the question.

15 Q. Okay. I don't have this marked as an exhibit  
16 yet. I'm going to mark this whole batch of EKGs as  
17 Exhibit 63. Okay? I'm sorry. I don't have copies. We  
18 can get copies at the break.

19 (EXHIBIT NO. 63 MARKED)

20 MS. RUSNAK: Is there a Bates stamp number  
21 or anything we can identify it by?

22 MR. MORIARTY: No, not that I can see.

23 Oh. You know what? It's not going to help you very  
24 much, Cyndi.

25 MS. RUSNAK: All right.

1 MR. MORIARTY: The one I'm about to ask  
2 him says MVSLE 2831.

3 MS. RUSNAK: Believe it or not, I can find  
4 it with that.

5 Q. (BY MR. MORIARTY) It's a July 30, 2007, EKG.  
6 Does she have tachycardia at that point?

7 A. Yes.

8 Q. September 4th, 2007, does she have tachycardia  
9 at that point?

10 A. Yes.

11 Q. October 14th, 2007, does she have tachycardia  
12 at that point?

13 A. Yes.

14 Q. All right. So, when we get back to Exhibit  
15 20 -- when we get back to Exhibit 38, the EKG from  
16 January 22nd, 2008, tell me what the other possible  
17 causes of her tachycardia are besides digoxin excess.

18 A. There are a myriad of causes of tachycardia.

19 Q. Can you name two or three?

20 A. Anemia, blood loss, heart failure, shock from  
21 any source.

22 Q. Okay. Other than digoxin excess, can you name  
23 any possible other causes of volume overload? And I'm  
24 specifically referring to January of 2008.

25 A. Other causes that this particular patient had

1 or other causes in general?

2 Q. Well, let's try to stick with this patient.

3 A. Decompensated congestive heart failure.

4 Q. Okay. Anything else?

5 A. Not that I can remember.

6 Q. Could volume overload be -- happen secondary to  
7 dietary or medical noncompliance?

8 A. In the setting of heart failure?

9 Q. Yes.

10 A. Yes.

11 Q. Okay. Back when I was here asking you  
12 questions in 2009, I asked whether you were aware of any  
13 tests on Mimi Vega's Digitek; and you said you weren't  
14 aware of any. Have you become aware of any tests on  
15 Mimi Vega's Digitek tablets since the fall of 2009?

16 A. No.

17 Q. Do you know between 2006 and 2008 how many  
18 patients at Texas Heart were taking Digitek?

19 A. No.

20 Q. Do you know how many were taking -- do you know  
21 how many -- I'm sorry. Of your own specific patients,  
22 between 2006 and 2008, do you know how many of them were  
23 taking Digitek?

24 A. No.

25 Q. Have you sent any digoxin manufacturer a -- or

Reynolds Delgado, M.D.

May 25, 2011

Page 235

1 the FDA an adverse event report regarding digoxin since  
2 the fall of 2009?

3 A. No.

4 Q. Do you know whether anybody at Texas Heart or  
5 St. Luke's Hospital looked into whether there was any  
6 sort of spike in digoxin toxicity between 2006 and 2008  
7 amongst its patient population?

8 A. I don't.

9 Q. And you didn't do such an inquiry?

10 A. Correct.

11 Q. If there had been some sort of spike in digoxin  
12 toxicity, is that the sort of medical trend that would  
13 come to your attention for whatever reason as a staff  
14 member or a member of Texas Heart?

15 A. Possibly, yes.

16 Q. Let's talk about the DIG trial and Dr. Adams'  
17 paper. Okay?

18 A. Yes.

19 Q. When was the last time you read the DIG --

20 MR. MORIARTY: And that's capital D,  
21 capital I, capital G.

22 Q. (BY MR. MORIARTY) -- trial?

23 A. It's been awhile.

24 Q. I have it with me. I have just a few questions  
25 for you about it. Okay?

1 A. Yes.

2 Q. There's a copy of the DIG trial. It is Exhibit  
3 49.

4 A. (Witness reviewing document).

5 Q. So, on the left, we have something that's  
6 typically called in a scientific paper the abstract;  
7 correct?

8 A. Yes.

9 Q. And in the "Results" section, sixth line down,  
10 it says (Reading): In the digoxin group, there was a  
11 trend toward a decrease in the risk of death attributed  
12 to worsening heart failure.

13 Correct?

14 A. Yes.

15 Q. All right. And then at the bottom, there's a  
16 section called Conclusions; and that's just the overall  
17 conclusion of this paper in a summary form; is that  
18 right?

19 A. Yes.

20 Q. Now, in the second column, they identify the  
21 brand of digoxin that they used in the study as Lanoxin  
22 from GlaxoWellcome, do they not?

23 A. Yes.

24 Q. And do you have any idea how many papers have  
25 been written subsequent to this DIG trial that have used

1 the data generated by this DIG trial to analyze digoxin  
2 from various angles?

3 A. No.

4 Q. All right. The Kirkwood Adams and Mihai  
5 Gheorghide paper that we talked about at your first  
6 deposition is an article that takes data from this DIG  
7 trial and analyzes it for a different purpose; correct?

8 A. Correct.

9 Q. So, let's go to the second page of this  
10 article. First, let's talk about outcomes. It's in  
11 small print. And it says (Reading): The primary  
12 outcome studied in the main trial was mortality. The  
13 secondary outcomes were mortality from cardiovascular  
14 causes, death from worsening heart failure,  
15 hospitalization for worsening heart failure, and  
16 hospitalization for other causes, in particular,  
17 suspected digoxin toxicity.

18 Do you see that?

19 A. Yes.

20 Q. Did I read it correctly?

21 A. Yes.

22 Q. So, they apparently distinguish between  
23 mortality from cardiovascular causes and death from  
24 worsening heart failure; is that correct?

25 A. Yes.

1 Q. A cardiovascular cause that may not be related  
2 to worsening heart failure could, for example, be an  
3 arrhythmia; is that right? That's one example?

4 A. Yes.

5 Q. So, a myocardial infarction could be another  
6 example; is that right?

7 A. Yes.

8 Q. And when patients have what is referred to as  
9 digoxin toxicity or digoxin excess, is arrhythmia the  
10 most common adverse cardiovascular reaction?

11 A. Yes.

12 Q. Okay. So, let's go back up the column to the  
13 very last sentence in the section above "Randomization."  
14 It says (Reading): The criteria for exclusion from the  
15 study have been published previously.

16 Do you see that?

17 A. I'm sorry. Which page?

18 Q. We're still on the second page. If you go up,  
19 last sentence near where your finger is.

20 A. Okay.

21 Q. (Reading): The criteria for exclusion from the  
22 study have been published previously.

23 Do you see that?

24 A. Yes.

25 Q. Okay. Now, let's go back to Page 530. Page

1 numbers are in the lower left. There's a column -- a  
2 title called "Serum Digoxin Levels." Do you see that?

3 A. Yes.

4 Q. And the last sentence says (Reading): At one  
5 month, 88.3 percent of the patients in the digoxin group  
6 had serum digoxin levels within the therapeutic range of  
7 .5 to 2.0 nanograms per milliliter.

8 Did I read that correctly?

9 A. Yes.

10 Q. So, the range that they used as therapeutic was  
11 .5 to 2; right?

12 A. Yes.

13 Q. All right. Let's go to 531 in the "Discussion"  
14 section. The second sentence says (Reading): There  
15 were fewer deaths due to worsening heart failure in the  
16 digoxin group.

17 Did I read that correctly?

18 A. Correct.

19 Q. Okay. And then skip one sentence and go down.  
20 It says (Reading): The risk of hospitalization,  
21 especially for worsening heart failure, was reduced with  
22 digoxin treatment.

23 Do you see that?

24 A. Correct.

25 Q. All right. And in general, that was sort of



1 the conclusion of the digoxin trial, that while digoxin  
2 did not reduce mortality overall, it reduced  
3 hospitalizations from heart failure; correct?

4 A. Yes.

5 Q. All right. So, let's go to Exhibit 49-A, which  
6 is the previous publication referred to in the DIG trial  
7 that has the exclusion criteria. Okay?

8 A. Okay.

9 Q. And let's go to Page 81, Item 7. It's called  
10 "Monitoring of Serum Digoxin Levels for Both Therapeutic  
11 Reasons and Patient Safety in a Blinded Trial." Are you  
12 there?

13 A. Yes.

14 Q. The second sentence after that italicized  
15 material says (Reading): Because high serum digoxin  
16 levels without clinical signs of toxicity do not prove  
17 toxicity, The Core Group felt that the value of the test  
18 was primarily to confirm toxicity in patients with a  
19 clinical suspicion.

20 Did I read that correctly?

21 A. Yes.

22 Q. Do you agree with it?

23 A. Yes.

24 Q. Okay. So, on the next page, there is a table  
25 which has the exclusion criteria. And in a big trial

1 like this, there are some people who are included and  
2 some who are not included for various reasons; correct?

3 A. Correct.

4 Q. And this is controlled fairly vigorously so  
5 that you can have consistency and hopefully prove with  
6 randomized prospective data a particular point; correct?

7 A. Yes.

8 Q. Okay. So, in the exclusion criteria, go down  
9 to Item 14, please. What does that say?

10 A. (Reading): Current treatment with intravenous  
11 inotropic agents.

12 Q. As of January, 2008, was Mimi Vega being  
13 treated with intravenous inotropic agents?

14 A. I don't remember.

15 Q. Okay. Wasn't she on home milrinone intravenous  
16 therapy from the October hospitalization through and  
17 into her admission in which she got her LVAD in  
18 February?

19 A. I don't remember.

20 Q. If she was on intravenous inotropic agents at  
21 that point, she would not have qualified for the DIG  
22 trial; correct?

23 A. Correct.

24 Q. And then Item 16 says (Reading): Need for  
25 cardiac surgery.

Reynolds Delgado, M.D.

May 25, 2011

Page 242

1 Does it not?

2 A. Correct.

3 Q. In January and February of 2008, wasn't your  
4 team working Mimi Rivera-Vega up for possible heart  
5 transplant, if she could get on the list?

6 A. Yes, that's my recollection.

7 Q. And, so, that would be a need for cardiac  
8 surgery; correct?

9 A. Yes.

10 Q. And then No. 17, if you're actually on the  
11 transplant list, you would not have been eligible for  
12 the DIG trial; correct?

13 A. Yes.

14 Q. So, after February 5th, 2008, she wouldn't have  
15 been eligible for entry into this trial; right?

16 A. Correct.

17 Q. Patients have varying degrees of clinical  
18 impairment from heart failure, do they not?

19 A. Yes.

20 Q. And, so, doctors like yourselves in large  
21 group -- doctors like yourselves in large groups have  
22 come up with some ratings systems for patients, have  
23 they not?

24 A. Yes.

25 Q. Such as the New York Heart Association

1 guidelines?

2 A. Yes.

3 Q. And Mimi Vega, for almost all of 2007 and into  
4 2008, was NYHA Class IV, was she not?

5 A. I don't remember; but I don't believe she was  
6 continuously Class IV throughout that entire period, no.

7 Q. Okay. And if you go back to Exhibit 49, the  
8 DIG trial, it says on the last page (Reading): Only 2  
9 percent of the patients were in NYHA functional Class  
10 IV, and 30.6 percent were in Class III.

11 Do you have any reason to disagree with that?

12 A. No.

13 Q. So, the people who were in NYHA IV would have  
14 been -- not to put too fine a point on it -- sicker than  
15 the far greater number of people in the trial; correct?

16 A. Yes.

17 Q. And do NYHA IV patients, in general, have a  
18 higher risk for rehospitalization for exacerbations of  
19 or worsening heart failure?

20 A. Yes.

21 Q. Now let's talk about the Adams paper.

22 By the way, let me stick with the DIG trial for  
23 a minute. The -- does the DIG trial paper say anywhere  
24 within it that they initiated an investigation into the  
25 dose strength of the Lanoxin tablets for patients who

1 had serum digoxin levels of 1.2 or greater?

2 A. No.

3 Q. Is there anything in the DIG trial paper itself  
4 that says -- breaks out the number of people who  
5 developed cardiogenic shock at any DIG level?

6 A. No.

7 Q. Okay.

8 MS. RUSNAK: Can we take a quick break?

9 MR. MORIARTY: Sure. Absolutely.

10 (RECESS FROM 2:52 P.M. TO 2:59 P.M.)

11 Q. (BY MR. MORIARTY) That's Exhibit 17 from your  
12 first deposition. Kirkwood Adams is the lead author;  
13 correct?

14 A. Yes.

15 Q. Now, down towards the end, there's another  
16 author named Mihai Gheorghide; is that correct?

17 A. Yes.

18 Q. Do you know Dr. Gheorghide?

19 A. Yes.

20 Q. Is he a reputable cardiologist?

21 A. Yes.

22 Q. Have you ever practiced with him?

23 A. No.

24 Q. Have you ever co-authored any articles with  
25 him?

Reynolds Delgado, M.D.

May 25, 2011

Page 245

1 A. No.

2 Q. Have you ever co-authored any articles with  
3 Kirkwood Adams?

4 A. No.

5 Q. All right. Let's go to -- I have a lot of  
6 questions about this. Let's go first to the abstract,  
7 and it says (Reading): Background: Controversy  
8 continues concerning the clinical utility of digoxin in  
9 women with heart failure.

10 Do you see that?

11 A. Yes.

12 Q. Did you agree with that when this was published  
13 in 2005?

14 A. Yes.

15 Q. Was it still true in 2007 and '08?

16 A. Yes.

17 Q. Now, in the "Results" section of the abstract,  
18 the second sentence says (Reading): Averaging hazard  
19 ratios across serum concentrations -- and it goes on to  
20 talk about the numbers.

21 Do you see that?

22 A. Yes.

23 Q. So, if I understand their method, what they did  
24 is for people whose serum concentrations were .5 to .9,  
25 they averaged the serum -- or the hazard ratios; is that

1 right?

2 A. Yes.

3 Q. So, for example, if people at serum levels of  
4 .5 had a hazard ratio of whatever and people had a --  
5 who had serum levels of .9 had a presumably higher  
6 hazard ratio, for purposes of this, they averaged them;  
7 correct?

8 A. Yes.

9 Q. So, when we get down to the group we're most  
10 concerned about in this case, the serum digoxin group  
11 from 1.2 to 2.0, those were also averaged; is that  
12 right?

13 A. I don't know.

14 Q. Would you assume that if they averaged the  
15 .5-.9s, that they would average the 1.2 to 2s?

16 A. No.

17 Q. How would you be able to compare if you did not  
18 perform the same mathematical calculations on both  
19 groups?

20 A. I don't know.

21 Q. All right. I'm sure that when you went to  
22 college, you probably took statistics. Tell me the  
23 extent of your statistical training after college.

24 A. There is some statistical training in medical  
25 school, not a specific course on it but more so training

1 during the course of other courses.

2 Q. So that you know how to read these kind of  
3 things and make sense of them?

4 A. Yes.

5 Q. You don't have any other training other than  
6 what you received in medical school and regular  
7 training; correct?

8 A. Yes.

9 Q. When you publish papers and you have a lot of  
10 data to analyze, who does the actual data analysis for  
11 you?

12 A. The staff statistician at Texas Heart  
13 Institute.

14 Q. All right. Who is that?

15 A. Previously, William Vaughn; currently, Mac  
16 Elayda.

17 Q. All right. Is there anywhere in the  
18 Adams-Gheorghide paper interpreting the DIG trial that  
19 indicates that they questioned the dose levels of the  
20 Lanoxin tablets that had been used on these patients?

21 A. No.

22 Q. Is there anywhere in the Adams and Gheorghide  
23 paper, Exhibit 17, that concludes that serum levels at  
24 1.2 or above was some evidence that their tablets were  
25 out of specification?



1 A. No.

2 Q. On the first page in the lower right-hand  
3 corner, the beginning of the last paragraph, it says  
4 (Reading): We retrospectively analyzed data from the  
5 DIG trial with continuous multivariable analysis,  
6 et cetera.

7 Do you see that?

8 A. Yes.

9 Q. Is a retrospective analysis different from a  
10 prospective randomized study?

11 A. Yes.

12 Q. Does it have different levels of scientific  
13 gravitas, so to speak?

14 A. It depends.

15 Q. Are retrospective studies generally considered  
16 to be hypothesis generating?

17 A. It depends in this case because it's a  
18 retrospective study of a prospective study.

19 Q. Okay. In general, are retrospective studies  
20 only hypothesis generating?

21 A. If they are retrospective studies only.

22 Q. All right. Let's go to the second page.  
23 Right-hand column, last sentence in the "Study  
24 Population" section, it says (Reading): There were 306  
25 women who had serum digoxin concentrations between .5

1 and 2.0.

2 Do you see that? It's referring to 1,110 men  
3 and 306 women who had serum -- SDCs greater than or  
4 equal to .5 to 2.0 nanograms per milliliter. Do you see  
5 that?

6 A. Yes.

7 Q. Do you know what percentage of those patients  
8 were NYHA Class IV?

9 A. No.

10 Q. Let's go to Page 501, please, right-hand  
11 column. Ninth line from the top of the second column,  
12 it says (Reading): Our study cannot define the  
13 mechanisms responsible for the adverse effect of higher  
14 serum digoxin concentrations.

15 Do you see that?

16 A. Yes.

17 Q. What does that mean to you?

18 A. Using this data, they are unable to determine  
19 the actual mechanism by which the higher concentrations  
20 lead to adverse events.

21 Q. Okay. Let's go to Page 502, please. The last  
22 sentence above Table 4 says (Reading): As with any  
23 retrospective nonrandomized study, well-known factors  
24 could have confounded our results.

25 Do you see that?

Reynolds Delgado, M.D.

May 25, 2011

Page 250

1 A. Yes.

2 Q. So, they're calling this a retrospective  
3 nonrandomized study, are they not?

4 A. Yes.

5 Q. So, at least in theory, this could be  
6 hypothesis generating only; right?

7 A. Not necessarily.

8 Q. Okay. Going down in that same section, it says  
9 (Reading): Our modeling analysis did investigate serum  
10 concentration as a continuous variable with arbitrary  
11 cut points used only to illustrate the clinical  
12 importance of the observed relationship.

13 Do you see that?

14 A. Yes.

15 Q. Do you know what they're referring to in this  
16 by "arbitrary cut points"?

17 A. No.

18 Q. Is it reasonable to conclude that they are  
19 using 1.2 as a serum level as an arbitrary cut point?

20 A. I don't know.

21 Q. It says here (Reading): Worse outcomes in  
22 patients with high SDCs could be related to underlying  
23 renal disease or more severe clinical HF.

24 Do you see that?

25 A. Yes.

1 Q. Do you agree with it?

2 A. Yes.

3 Q. And if only 2 percent of the patients in the  
4 DIG trial were NYHA IV and we don't know how many of the  
5 women that they analyzed were NYHA IVs, would you agree  
6 that Mimi Vega, as an NYHA IV, would fall in the  
7 category of more severe clinical heart failure as  
8 they're referring to here at Page 503?

9 A. I think the question's mistaken. If you could  
10 ask the question again or reword the question.

11 Q. Sure.

12 There -- in these pages what they're doing is  
13 searching for some rationale for why patients at higher  
14 serum levels seemed to have a higher mortality level;  
15 correct?

16 A. Yes.

17 Q. Okay. And one of the explanations might be  
18 that that group of people had more severe clinical heart  
19 failure to begin with; correct?

20 A. Possibly.

21 Q. Okay. And patients in New York Heart  
22 Association Class IV would have generally more severe  
23 clinical heart failure, would they not?

24 A. Than III, II, or I, yes.

25 Q. Correct.

1           Okay. So, here where they are -- as in almost  
2   every paper -- cautioning about the limits of their  
3   study, they don't know and we don't know whether the  
4   increased mortality was attributable to more severe  
5   heart failure in those patients; correct?

6           MS. RUSNAK: Objection, form.

7           A. That would depend.

8           Q. (BY MR. MORIARTY) On what?

9           A. On whether you mean due to, as I think you  
10   said, to relate to causation.

11          Q. Do patients in NYHA IV, in general, have higher  
12   mortality rates than patients who are NYHA III?

13          A. Yes.

14          Q. Does that include from worsening heart failure?

15          A. Yes.

16          Q. Let's go to Page 504. It says here (Reading):  
17   Beta blockers were not part of the usual management of  
18   heart failure at the time of the DIG study.

19                 Mimi was on beta blockers in 2007 and early  
20   2008, was she not?

21          A. Yes.

22          Q. And if you go to the next paragraph from where  
23   I just was, it starts (Reading): Some might wonder why  
24   we would bother with digoxin.

25                 If you go down ten lines, sentence starts

1 (Reading): Because the morbidity...

2 A. Yes.

3 Q. (Reading): Because the morbidity benefit seems  
4 greater and safety more likely at lower serum  
5 concentrations, administering low doses of .125  
6 milligrams a day or less to achieve serum concentrations  
7 from .5 to .9 nanograms per milliliter is indicated.

8 Do you see that?

9 A. Yes.

10 Q. Do you agree with it?

11 A. Yes.

12 Q. Is there literature out there that basically  
13 says that .125 milligrams a day once you reach steady  
14 state should lead to a serum digoxin concentration of  
15 approximately .8 in patients who do not have a renal  
16 compromise?

17 A. I don't know.

18 Q. Do you know what dose you had prescribed to  
19 Mimi Rivera-Vega starting on January 13th, 2008?

20 A. I don't remember.

21 Q. I want you to assume -- and I'll show you the  
22 prescription slip later -- that it was .25 milligrams a  
23 day. Do you know why you prescribed that higher dose at  
24 that point?

25 A. One of the biggest factors is size, body size

1 and age. That would likely be the reason.

2 Q. Okay.

3 A. Young age, large body size.

4 Q. Now, the text of this article doesn't address  
5 the serum levels of 1.0 and 1.1, does it? The cut  
6 points are .5 to .9 and 1.2 to 2; right?

7 A. Correct.

8 Q. Do you know why that is?

9 A. No.

10 Q. Does either the DIG trial or this Adams and  
11 Gheorghiade paper say that the people who died at the  
12 higher serum levels died of worsening heart failure as  
13 opposed to arrhythmias or other cardiovascular causes?

14 A. This paper makes reference to that possibly.

15 Q. Where?

16 A. Page 503, starting with the sentence (Reading):  
17 Worse outcomes...

18 Q. Okay. The sentence we were talking about  
19 before?

20 A. Yes.

21 Q. Okay. Do you know Dr. Semigran, Marc Semigran  
22 from Mass General?

23 A. No.

24 Q. Have you read any report or testimony from him  
25 in this case?

1 A. No.

2 Q. Now, when we talk -- the last thing I want to  
3 really talk about in detail about this article is the  
4 hazard ratios. If the hazard ratio is 1.0, is that the  
5 line of no effect?

6 A. Yes.

7 Q. All right. So, an HR of below 1 is either  
8 beneficial or no effect, and above 1 is detrimental;  
9 correct?

10 A. It depends.

11 Q. Depends on what?

12 A. The statistical significance.

13 Q. Okay. If a hazard -- you know what a  
14 confidence interval is?

15 A. Yes.

16 Q. If a confidence interval encompasses the HR of  
17 1.0, does it make the findings statistically significant  
18 or not?

19 A. It would depend.

20 Q. Okay. Would you defer to a statistician on  
21 this point?

22 A. Yes.

23 Q. So, assuming that they -- the authors, for  
24 purposes of this work, averaged the hazard ratios in  
25 both groups, the hazard ratio of 1.33 for the group from



1 serum levels 1.2 and 2 is not the hazard ratio for the  
2 serum level of 1.2 alone; correct?

3 A. I don't know.

4 Q. Okay. Let's look at Figure 2 on Page 501 of  
5 Exhibit 17. Okay? This plots the point estimates and  
6 confidence intervals in men and women for the hazard  
7 ratio for death on digoxin versus placebo at various  
8 serum digoxin concentrations; correct?

9 A. Yes.

10 Q. All right. Now, if you go to the serum level,  
11 which is the bottom of these axes, the horizontal axis,  
12 and you go up, the confidence interval for both men and  
13 women straddles between -- somewhere between a hazard  
14 ratio of .8 and 1., say, 4, doesn't it?

15 A. Straddles the line of unity, yes.

16 Q. Okay. Between approximately .8 and 1.4;  
17 correct?

18 A. Yes.

19 Q. So, do you have an opinion today, to a  
20 reasonable degree of medical probability and statistical  
21 probability, whether a serum digoxin concentration of  
22 1.2 is statistically significant proof of a higher  
23 mortality at that serum level?

24 MS. RUSNAK: Objection, form.

25 A. I don't understand the question.

1 Q. (BY MR. MORIARTY) Okay. Well, your options are  
2 to have an opinion, in which case I'll ask you to  
3 explain it; to have no opinion; or to defer to a  
4 statistician. As --

5 MS. RUSNAK: Objection --

6 Q. (BY MR. MORIARTY) As I read this, at the serum  
7 level of 1.2 -- let me take a step back. My  
8 understanding of this type of graph is that because of  
9 all the variables involved in a trial like this, when  
10 you can't be 100 percent certain of the results, there's  
11 a confidence interval -- in other words, a range of "is  
12 this accurate and statistically significant"; and it has  
13 an upper range and a lower range. Is that your  
14 understanding?

15 A. It's a statistical tool --

16 Q. Okay.

17 A. -- and common sense.

18 Q. Okay. And does the statistical tool  
19 essentially say what I'm saying here?

20 A. Sometimes.

21 Q. Okay. Well, in this case, for both men and  
22 women, the confidence interval at a serum digoxin level  
23 of 1.2 is below the 1.0 line. I keep forgetting what  
24 you're calling it.

25 A. Unity.

1 Q. Unity.

2 In other words, there's no effect on mortality  
3 at a serum level of 1.2 if it's below unity; correct?  
4 And then above the line for men, the hazard ratio is  
5 somewhere in the nature of 1.2; and for women, it's  
6 somewhere in the nature of 1.4; correct?

7 A. Yes.

8 Q. But when you take the entire range, because the  
9 confidence interval encompasses unity means that it is  
10 not statistically significant; is that correct?

11 A. No.

12 Q. So, what's your understanding?

13 A. Of?

14 Q. The statistical significance of a serum level  
15 of 1.2 as to increased mortality in men or women as it  
16 pertains to this paper.

17 A. (Reading): Retrospective analysis of data from  
18 the DIG trial indicates a beneficial effect of digoxin  
19 on morbidity and no excess mortality in women at serum  
20 concentrations from .5 to .9 nanograms per milliliter;  
21 whereas, serum concentrations greater than or equal to  
22 1.2 nanograms per milliliter seem harmful.

23 Q. Okay. You're reading from the abstract?

24 A. Yes.

25 Q. That's the text, correct, based on average

1 hazard ratios; correct?

2 A. No.

3 Q. You don't think that's based on average hazard  
4 ratios?

5 A. It's not the text.

6 Q. You're reading from the abstract; correct?

7 A. Yes.

8 Q. Where they're talking about average hazard  
9 ratios; correct?

10 A. No.

11 Q. It says right here (Reading): Averaging hazard  
12 ratios.

13 Do you have some indication from this paper or  
14 from the authors or from the DIG trial or any other  
15 scientific information that these hazard ratios weren't  
16 averaged?

17 A. I don't know.

18 Q. All right. So, what I'm trying to ask you,  
19 Dr. Delgado, is not the range of serum levels from 1.2  
20 to 2; I'm asking you about a specific serum level, 1.2,  
21 which happens to be what Mimi Rivera-Vega had in January  
22 and February of 2008, and on which you based your  
23 opinions in this case. Okay? So, let's look at serum  
24 levels of 2 in Figure 2 on Page 501. Okay? You see  
25 that?

Reynolds Delgado, M.D.

May 25, 2011

Page 260

1 A. Yes.

2 Q. Okay. And the dark dots are women. So, at a  
3 serum level of 2.0 nanograms per milliliter, the hazard  
4 ratio is somewhere between 1.5 and 1.6 for women;  
5 correct?

6 A. Yes.

7 Q. And the confidence intervals for both men and  
8 women at serum levels of 2.0 are above unity; correct?

9 A. Yes.

10 Q. But as you go back down the slope, when you get  
11 to a serum level of 1.4, the confidence intervals are  
12 clearly at the lower range below unity, are they not?

13 A. Yes.

14 Q. And then at a serum level of 1.2, they're below  
15 unity -- we've already discussed this -- from about --  
16 for women .8 to 1.4; correct?

17 A. Yes.

18 Q. Now, just for the serum level of 1.2 nanograms  
19 per milliliter, is this statistically significant?

20 A. I don't know.

21 Q. If they had not studied anything other than  
22 1.2, if they had a whole group of 1.2 serum levels and  
23 there was no averaging question involved, would you  
24 agree that this is not statistically significant?

25 A. I don't know.

1 Q. Okay.

2 A. I want to change that. Yes, the statistical  
3 significance is as it's stated in the conclusion.

4 Q. For a serum level only of 1.2?

5 A. Yeah, equal to or greater than 1.2.

6 Q. When you say the "conclusion," you're talking  
7 about in the abstract?

8 A. Either.

9 Q. Okay. But when they reach that conclusion,  
10 they're talking about -- okay. Never mind. Withdraw  
11 that.

12 If a patient fails to take medications as  
13 prescribed, can it lead to exacerbation of heart  
14 failure?

15 A. Yes.

16 Q. Could it lead to cardiogenic shock?

17 A. Yes.

18 Q. Can I have that back, please?

19 A. Yes.

20 Q. I have Exhibit 23 here if you need to refer to  
21 it. It's the discharge summary of the hospitalization  
22 January 22 through 25, 2008. When she went to the  
23 hospital that time, did she have complaints consistent  
24 with congestive heart failure?

25 A. Yes.

Reynolds Delgado, M.D.

May 25, 2011

Page 262

1 Q. Was that the diagnosis?

2 A. Yes.

3 Q. Was that what you treated her for?

4 A. Yes.

5 Q. How many potential causes are there for an  
6 exacerbation of heart failure?

7 A. They would fall under three general  
8 categories -- medication related, diet related, or their  
9 comorbid illnesses.

10 Q. I assume there's a -- also an "etiology  
11 unknown" category?

12 A. Sure, yes.

13 Q. All right. Now, you have in front of you  
14 Exhibit 23, the discharge summary. And it says here  
15 that she had not had her Lasix for the last four to five  
16 days and has had a weight increase of 4 to 5 pounds. Do  
17 you see that?

18 A. Yes.

19 Q. And she was being admitted with CHF and volume  
20 overload; correct?

21 A. Yes.

22 Q. Patients can get volume overload when they  
23 don't take their diuretics; is that right?

24 A. Yes.

25 Q. Lasix is a diuretic?

1 A. Yes.

2 Q. I'm showing you Exhibit 20. This is a history  
3 and physical from an admission to St. Luke's Jan 5th of  
4 2003 with you as the admitting physician. Do you see  
5 that?

6 A. Yes.

7 Q. And several lines from the top of the "History  
8 of Present Illness," it says (Reading): She had gone  
9 out of town for about two days, only planned to stay for  
10 an afternoon and ended up staying, during which she  
11 didn't have her daily medications, including her  
12 diuretics.

13 Correct?

14 A. Yes.

15 Q. And that -- at that time that medication  
16 indiscretion, if you will, was one of the precipitating  
17 factors of this heart failure exacerbation; is that  
18 right?

19 A. Yes.

20 Q. So, does this fall under the medication related  
21 or diet potential cause of a heart failure exacerbation?

22 A. Yes.

23 Q. Showing you Exhibit 21. This is a discharge  
24 summary from an admission to St. Luke's January of 2004  
25 with Dr. Naik, N A I K, as the attending. Do you see



Reynolds Delgado, M.D.

May 25, 2011

Page 264

1 that?

2 A. Yes.

3 Q. Do you know Dr. Naik?

4 A. Yes.

5 Q. All right. And under the "Hospital Course," it  
6 says that (Reading): She had become acutely worse a  
7 week prior to admission, added that she had been off her  
8 medications for the last month, and gives the reason for  
9 that.

10 Do you see that?

11 A. Yes.

12 Q. And, so, this medication issue was one of the  
13 precipitating factors for this congestive heart failure  
14 exacerbation; is that correct?

15 A. Yes.

16 Q. And then Exhibit 22 is a discharge summary from  
17 St. Luke's July of 2006 with you as the admitting  
18 physician; correct?

19 A. Yes.

20 Q. And under the "Clinical Summary," it gives her  
21 age, her disease, and that she ran out of her  
22 medications five days ago and now has developed  
23 shortness of breath and chest congestion. Do you see  
24 that?

25 A. Yes.

1 Q. So, was a medication issue a precipitating  
2 cause of this admission for heart failure exacerbation?

3 A. Yes.

4 Q. What are some of the risks of obstructive sleep  
5 apnea?

6 A. It can cause pulmonary hypertension and right  
7 heart failure, arrhythmias.

8 Q. I'm sorry. Is that three things?

9 A. Yes.

10 Q. Pulmonary hypertension, right heart failure,  
11 and arrhythmias?

12 A. Yes.

13 Q. Okay. Do you, as a cardiologist, understand  
14 why that is the case?

15 A. Yes.

16 Q. Why is that? Not why is it that you know, but  
17 why is it that OSA increases those risks?

18 A. OSA causes periods of a hypoxia or low oxygen  
19 level during sleep, and that leads to pulmonary  
20 arteriolar vasodilation -- I'm sorry --  
21 vasoconstriction, which causes the pulmonary  
22 hypertension. That then can cause right ventricular  
23 overload and dysfunction, which leads to the right heart  
24 failure. That then can cause tricuspid regurgitation  
25 and right atrial hypertension, which can lead to the

1 arrhythmias.

2 Q. Okay. All right. I'm about to shift topics to  
3 talk about milrinone. Do you want to take a break  
4 before we do that, or are you good?

5 A. I'm good.

6 Q. All right. We know that when Mrs. Vega was  
7 admitted to St. Luke's in October of 2007, she was  
8 prescribed intravenous milrinone; and then when she was  
9 discharged, she was sent home on it; correct?

10 A. Yes.

11 Q. All right. When you go through the thought  
12 process that leads you to make that recommendation and  
13 prescription, do you try to do a projection of how long  
14 it's going to take someone like Mimi to get on the  
15 transplant list and then to get a heart?

16 A. No.

17 Q. Do you just say to yourself essentially, "I  
18 think she needs this therapy. We're going to prescribe  
19 it and do the best we can to move the process along"; or  
20 what's the thought process?

21 A. The milrinone is generally used as bridge to  
22 transplant. It's impossible to determine how long until  
23 someone gets a transplant.

24 Q. Okay. But since she was not even on the  
25 transplant list at that point, was it reasonable for you

1 to predict that she'd be on the IV milrinone, if you  
2 left her on it, for 100 days or more?

3 A. If she required it, yes.

4 Q. Okay. Showing you Exhibit 30. Okay. This  
5 is -- I know it's a little hard to read, but this is a  
6 progress note from November of -- well, it's a note from  
7 November of 2007. Is some of this your writing?

8 A. Yes.

9 Q. Okay. So, on the right in that sort of open  
10 area, tell me what your writing says. I think it's  
11 "alert" at the top. Tell me what it says the rest of  
12 the way down.

13 A. (Reading): Feels better; less shortness of  
14 breath; mild pleuritic chest pain; vital signs stable;  
15 no jugular venous distension; chest rhonchi;  
16 cardiovascular rate rhythm; extremities, no cyanosis, no  
17 clubbing or edema; assessment plan: CHF, CMP.

18 Q. What's the CMP?

19 A. Cardiomyopathy.

20 Q. Okay.

21 A. Volume overload improved; to floor; milrinone,  
22 BTT.

23 Q. That's bridge to transplant?

24 A. Yes.

25 Q. Okay. And it says something about weight loss,

1 and then what does it say after that?

2 A. (Reading): Decreased nesiritide; secondary to  
3 low blood pressure.

4 Q. All right. And then on the left, it says, I  
5 think (Reading): Echo; severe mitral regurgitation  
6 and --

7 A. (Reading): Pulmonic regurgitation.

8 Q. Okay. (Reading): Will likely need LVAD --

9 A. Correct.

10 Q. (Reading): -- but will try again with?

11 A. (Reading): Metolazone and Lasix.

12 Q. All right. So, at this point, November of  
13 2007, you thought it was likely she was going to need an  
14 LVAD; is that correct?

15 A. Yes.

16 Q. Is that because she was not yet on the  
17 transplant list?

18 A. No.

19 Q. Why was it likely she was going to need an LVAD  
20 as of November -- I'm sorry. Let me rephrase that.

21 Why were you saying in your notes in November  
22 of 2007, it was likely she would need an LVAD?

23 A. When it becomes difficult or impossible to  
24 manage without it. And the LVADs can be used as a  
25 bridge to transplant or as a permanent therapy.

1 Q. All right. Did you assume she was dependent on  
2 milrinone?

3 A. No.

4 Q. How do you determine -- well, first of all, is  
5 it relevant at all whether the patient going home on a  
6 milrinone IV is dependent on milrinone?

7 A. I don't think it's relevant because that is not  
8 the determinant, whether they go home on it or not.  
9 It's not the determinant to whether they can be weaned.

10 Q. Why do -- why does the literature from time to  
11 time talk about weaning or attempts at weaning patients  
12 from IV milrinone?

13 A. You should always be weaned, if possible.

14 Q. Why?

15 A. It's a continuous intravenous medicine that  
16 requires an indwelling central venous line which is  
17 prone to infection and, secondly, because there are no  
18 data to support that it increases survival, only that it  
19 improves symptoms.

20 Q. Do you know whether anybody attempted to wean  
21 her from milrinone at St. Luke's Hospital in the fall of  
22 2007?

23 A. I don't remember.

24 Q. Whose responsibility would it have been with  
25 this patient to attempt that?

Reynolds Delgado, M.D.

May 25, 2011

Page 270

1 A. It would have likely been mine.

2 Q. Okay. I don't know if I've asked you this  
3 before, but St. Luke's is a teaching hospital; correct?

4 A. Yes.

5 Q. Does it have -- also have a fellowship program  
6 for cardiologists?

7 A. Yes.

8 Q. So, it has -- is there a medical school  
9 affiliated with St. Luke's, also?

10 A. Yes.

11 Q. So, they might have, you know, nurses, nurse  
12 practitioners, medical students, interns, residents,  
13 fellows, and attendings; correct?

14 A. Yes.

15 Q. In several disciplines, but certainly  
16 cardiology?

17 A. Yes.

18 Q. And -- okay. I'm going to show you Exhibit 36.  
19 This is the 2003 PDR on milrinone. Okay? I couldn't  
20 find it in any of the later books. Do you still  
21 prescribe milrinone to patients in whom you deem it  
22 appropriate?

23 A. Yes.

24 Q. Now, in -- it talks in the second column about  
25 plasma concentrations, steady state plasma milrinone

1 concentrations; and then it gives some numbers. Do  
2 doctors routinely draw and monitor plasma milrinone  
3 concentrations?

4 A. No.

5 Q. At the top under -- top right under "Warnings,"  
6 it says (Reading): Primacor -- which is milrinone --  
7 has not been shown to be safe or effective in the longer  
8 (greater than 48 hours) treatment of patients with heart  
9 failure.

10 And it goes on to talk about a multicenter  
11 trial. (Reading): There's no evidence that Primacor  
12 given by long-term continuous or intermittent infusion  
13 does not carry a similar risk.

14 In essence, in 2007, the way you're using  
15 milrinone with Mimi Vega, would it have been considered  
16 off-label use?

17 A. Probably, yes.

18 Q. Okay. And on the second page, if you go to  
19 "Adverse Reactions," left-hand column about two-thirds  
20 of the way down, "Cardiovascular Effects" (Reading):  
21 Patients receiving Primacor in Phase II and III trials,  
22 ventricular arrhythmias were reported in 12.1 percent;  
23 nonsustained v-tach, 2.8 percent, et cetera.

24 Do you see that?

25 A. Yes.



Reynolds Delgado, M.D.

May 25, 2011

Page 272

1 Q. So, nonsustained ventricular tachycardia is a  
2 potential reaction to milrinone, is it not?

3 A. Yes.

4 Q. Do you know what percentage of patients who are  
5 started on IV milrinone as bridge to transplant will  
6 eventually require an LVAD?

7 A. No.

8 Q. Does the use of milrinone for three months or  
9 more increase the risk of decompensation and need for  
10 LVAD placement?

11 A. Not that I know of.

12 Q. This is -- Exhibit 59 is a paper published in  
13 the "Journal of Cardiac Failure." Have you ever  
14 published anything in the "Journal of Cardiac Failure"?

15 A. I can't remember if I have or not.

16 Q. These articles are from Houston -- I mean these  
17 authors are from Houston at the Methodist DeBakey Heart  
18 Center. Is that -- and the Baylor College of Medicine.  
19 Is that a reputable heart treatment center?

20 A. Yes.

21 Q. The conclusion from the abstract says  
22 (Reading): This study suggests that chronic IV  
23 milrinone provides an adequate strategy as bridge to  
24 transplant if the waiting time is short, less than 100  
25 days; whereas, an elective ventricular assist device may

1 be a safer strategy for patients expected to wait  
2 longer.

3 Do you have any reason to disagree with their  
4 conclusion?

5 A. I don't -- I don't think their conclusion is  
6 definitive in any way.

7 Q. Okay. Under the "Discussion" section on Page  
8 841, it says (Reading): As shown by the time spent on  
9 milrinone in each subgroup, the success rates were best  
10 with one duration of three months or less. According to  
11 our results, long-term use of milrinone, greater than  
12 three months, increased the risk of further  
13 decompensation and necessitated VAD placement.

14 Do you agree or disagree with that statement?

15 A. I think that -- that result is what I would  
16 expect from their institution.

17 Q. Why?

18 A. The way they manage patients. It's very  
19 different than the way we do.

20 Q. And how is it different in this specific  
21 context with milrinone use?

22 A. One thing in particular is they use higher  
23 doses than we do; and they have a different weaning  
24 protocol than we do, which I think ours is better. And  
25 we use concomitant beta blockers, also. And there are

1 many other differences.

2 Q. What -- what difference does it make whether  
3 they use a different weaning protocol?

4 A. No one knows.

5 Q. Okay. Have you ever done a study of optimal  
6 length of time -- I'm sorry. Let me rephrase that  
7 question.

8 Have you ever done a study at Texas Heart of  
9 the appropriate length of time to continue patients on  
10 IV milrinone?

11 A. It would be an irrelevant study.

12 Q. Why?

13 A. It's not possible to make a definitive  
14 statement on that.

15 Q. Even if you did it retrospectively?

16 A. Either prospective or retrospective.

17 Q. All right. Well, Mrs. Vega was just at about  
18 three months of milrinone IV therapy at the end of  
19 January, 2008, was she not?

20 A. Yes.

21 Q. With no intervening attempts to wean to our  
22 knowledge?

23 A. Yes.

24 Q. Is the survival of patients on IV milrinone  
25 long term less than 10 percent at 12 months without

1 heart transplant?

2 A. It depends.

3 Q. What does it -- I don't have an extra copy of  
4 this, but I'll show you this. This is an article that  
5 you and Dr. Frazier wrote -- and Dr. Conti was another  
6 author -- in December of 2009 in "The New England  
7 Journal of Medicine." And it was comparing continuous  
8 flow versus pulsatile devices. Okay? But early in the  
9 article, you say (Reading): However, heart failure  
10 commonly progresses and becomes refractory to current  
11 treatments.

12 Do you agree with that?

13 A. I'd have to see it in context.

14 Q. Okay. Well, the sentence before it says  
15 (Reading): Medical and electronic -- medical and  
16 electrical therapies for systolic heart failure have  
17 improved outcomes and altered the natural history of the  
18 disease. However, heart failure commonly progresses and  
19 becomes refractory to current treatments.

20 A. Yes.

21 Q. (Reading): Continuous intravenous inotropic  
22 support may improve clinical status in the short term  
23 but results in a survival rate at one year of only 10 to  
24 30 percent.

25 A. Yes.

1 Q. Okay. And what is it that happens to the  
2 patients on IV milrinone as they get out to four, five,  
3 six, 12 months that leads to this lower survival rate?

4 A. The milrinone is thought to, while increasing  
5 the inotropic state of the heart, at the same time, it  
6 increases the work that the heart has to do and in doing  
7 so, decreases the lifespan of the heart.

8 Q. Okay. So, unless they get a ventricular assist  
9 device or a transplant, eventually they're going to have  
10 unremitting heart failure refractory to all treatments;  
11 correct?

12 A. It depends. There are some patients that don't  
13 follow that rule at all.

14 Q. Yeah. But it's a small percent. They are  
15 unlikely to survive 12 months?

16 A. Yes.

17 Q. Okay. Now, Mrs. Vega had her ventricular  
18 assist device placed February 11th, 2008. Nine days  
19 later, she was given IV milrinone. Can you tell me why?

20 A. Yes. It's used to treat right heart failure,  
21 also.

22 Q. All right. So, postplacement of her left  
23 ventricular assist device by Dr. Frazier in February,  
24 she developed right heart failure; correct?

25 A. Yes.

1 Q. Do you have an opinion as to why she  
2 developed -- an opinion to a probability as to why she  
3 developed right heart failure in February of 2008?

4 A. Only that it's common post-LVAD placement.

5 Q. Okay.

6 A. Over 15 percent of patients.

7 Q. All right. And then this -- this was repeated  
8 again from March 17th to April 4th. I believe at that  
9 point she was in her -- still had her first LVAD in.  
10 Would the reason have been the same, to treat right  
11 heart failure?

12 A. Yes.

13 Q. And then from May 18th to June 2nd, I believe,  
14 is when she had her second LVAD. Would the reason have  
15 been the same?

16 A. Yes.

17 Q. I've handed you Exhibit 56. This has to do  
18 with the REMATCH --

19 MR. MORIARTY: R E M A T C H, all caps.

20 Q. (BY MR. MORIARTY) -- study; correct?

21 A. Yes.

22 Q. On which you were a coauthor in 2005?

23 A. Yes.

24 Q. With Dr. Frazier?

25 A. Yes.

1 Q. Is there any particular reason why you seem to  
2 have so many papers coauthored with Dr. Frazier?

3 A. He and I are the -- the two that run the  
4 artificial heart service. I'm the Medical Director of  
5 mechanical support devices. He's the Surgical Director.

6 Q. Got it.

7 So, in the first column of the first page, it  
8 says (Reading): An estimated 100,000 individuals per  
9 year with end-stage HF who have a dismal prognosis with  
10 conventional medical treatment may be candidates for  
11 advanced therapeutic interventions.

12 Do you agree with that?

13 A. Yes.

14 Q. Did you still agree with that in 2007 and '08?

15 A. Yes.

16 Q. And then you go on to talk about the American  
17 College of Cardiology and American Heart Association  
18 consensus guidelines; correct?

19 A. Yes.

20 Q. Referring to stage D heart failure patients --

21 A. Yes.

22 Q. -- who had advanced structural heart disease  
23 and marked symptoms at rest despite maximal medical  
24 therapy; is that right?

25 A. Yes.

1 Q. And those were the patients who required  
2 specialized intervention, such as continuous IV  
3 inotropic therapy; is that correct?

4 A. Yes.

5 Q. Transplant or mechanical assist devices; is  
6 that right?

7 A. Yes.

8 Q. All right. I'll come back to that if I need  
9 it.

10 What is the actual purpose of the intraaortic  
11 balloon pump?

12 A. It depends on the clinical scenario.

13 Q. Well, let's get specific about Mimi  
14 Rivera-Vega. October of 2007, she comes into the  
15 hospital with an exacerbation of heart failure; and you  
16 did a cath and an IABP. What was the reason for that  
17 for her at that time?

18 A. I don't remember specifically.

19 Q. Let me see if I can find it because I probably  
20 have it.

21 Doctor, this is Exhibit 26.

22 MR. MORIARTY: Did I give you one?

23 MS. RUSNAK: Yeah, you did.

24 Q. (BY MR. MORIARTY) This is the procedure note  
25 for the right heart cath and the placement of the IABP



Reynolds Delgado, M.D.

May 25, 2011

Page 280

1 October, 2007. Do you see that?

2 A. Yes.

3 Q. So, at the time the indication going in was CHF  
4 decompensated, cardiomyopathy, and cardiogenic shock; is  
5 that right?

6 A. Yes.

7 Q. And the findings at the end were severely  
8 deranged hemodynamics; is that right?

9 A. Yes.

10 Q. And she was going to be admitted for management  
11 of her CHF; correct?

12 A. Yes.

13 Q. So, based on this, can you -- does this trigger  
14 any memory of what the purpose of the IABP was at that  
15 point?

16 A. There's two possibilities. One is it may have  
17 been done to determine candidacy and listing status for  
18 transplant, and second would have been to preserve organ  
19 function.

20 Q. Are you done with your answer?

21 A. Yes.

22 Q. When a patient has decompensated heart failure,  
23 it puts end-organ function at risk, does it not?

24 A. Yes.

25 Q. So, basically --

1           A.    I'm sorry.  I should redact that and say not  
2   necessarily.

3           Q.    Okay.  Frequently?

4           A.    Occasionally.

5           Q.    All right.  But it's a -- it's a way to measure  
6   hemodynamics and give the heart temporary rest -- is  
7   that right -- the balloon pump?

8           A.    No.  It -- it doesn't measure hemodynamics.  
9   It's a heart support device so that it will unload the  
10   heart --

11          Q.    Okay.

12          A.    -- to some degree, a lesser degree than an  
13   LVAD, for example.

14          Q.    All right.

15          A.    And you can, thus, determine what the future  
16   effects of an LVAD may be.

17          Q.    All right.  And can you tell from this  
18   procedure note what this added to your thinking about  
19   whether she was a candidate for transplant at the time?

20          A.    Not from this note.

21          Q.    Do you have memory that the only reason she was  
22   not on the transplant list as of the fall of 2007 was  
23   because she didn't meet the weight or BMI requirements?

24          A.    I don't remember if that was the only reason.  
25   That was certainly one of them.

1 Q. All right. We'll talk about that in a minute.

2 So, Exhibit 28 is that nurse's note that I  
3 referred to before.

4 You can just pile those here if you want.

5 A. (Witness complies).

6 Q. It says it's October 23rd and 24th, 2007. And  
7 do you know Paula Waller?

8 A. Yes.

9 Q. Is she a transplant nurse?

10 A. No.

11 Q. Transplant coordinator?

12 A. No.

13 Q. Transplant social worker?

14 A. Yes.

15 Q. All right. If you go into the background  
16 information on Page 1, it says (Reading): Mrs. Vega  
17 stated the transplant was mentioned to her as long ago  
18 as 2000 and several times since then, but her symptoms  
19 had responded to medical management heretofore.

20 A. Yes.

21 Q. We know that you had started taking care of her  
22 in 2002, I believe. Do you -- does this trigger any  
23 memory of when you would have first broached the subject  
24 of transplant with her?

25 A. No. I just don't remember.

1 Q. In your own practice, if a patient has  
2 nonischemic cardiomyopathy, which she did, with her  
3 degree of left ventricular dysfunction as far back as  
4 '96 to 2002, would you, as a matter of routine practice,  
5 at least plant the seed that this was a possibility down  
6 the line if her symptoms could not be controlled with  
7 medical management?

8 A. I would likely do the opposite, actually. I  
9 would probably tell them that they would not need a  
10 transplant.

11 Q. Okay.

12 A. Beyond likely that they would need a  
13 transplant.

14 Q. Okay. Well, obviously, there's other doctors  
15 she's seen. I'm just asking you whether -- what your  
16 practice would have been.

17 A. Yeah.

18 Q. Okay. I think you told me that the referral to  
19 the bariatric surgeons was, in part, to better prepare  
20 her for the transplant list. Am I correct?

21 A. Better -- better said, to make her a more  
22 suitable candidate.

23 Q. Okay. That procedure happened in 2007; right?

24 A. Yes.

25 Q. Do you know when you first referred her to a

1        bariatric surgeon?

2            A.    I don't remember specifically.

3            Q.    If I told you it was August 23rd of 2002,  
4        within a month or two of when you first started seeing  
5        her, would that surprise you?

6            A.    No.

7            Q.    This is Exhibit 53. It's a letter from the  
8        St. Luke's Hospital Clinical Director of Transplant  
9        Services to you; right?

10          A.    Yes.

11          Q.    About Mimi Rivera-Vega; is that correct?

12          A.    Yes.

13          Q.    And she was considered an indeterminate  
14        candidate for transplant at that time because her BMI  
15        was greater than 35 -- greater than 35; right?

16          A.    Correct.

17          Q.    Do they outline any other reasons why she was  
18        either not a candidate or an indeterminate candidate?

19          A.    No.

20          Q.    Showing you Exhibit 27. Is this your writing?

21          A.    Yes.

22          Q.    It's on an Operative/Procedure Note sheet from  
23        St. Luke's Hospital; correct?

24          A.    Yes.

25          Q.    And it's signed the 19th; is that right?

Reynolds Delgado, M.D.

May 25, 2011

Page 285

1 A. Right.

2 Q. So, this is probably describing the same  
3 catheterization that we discussed in Exhibit 26; is that  
4 right?

5 A. Yes.

6 Q. Okay. Different days by one, but you wouldn't  
7 have placed an IABP on back-to-back days; right?

8 A. Right.

9 Q. Okay. So, does this say (Reading): HD very  
10 poor?

11 A. Yes.

12 Q. In other words, hemodynamics very poor?

13 A. Right.

14 Q. Under the "IABP," does it say (Reading):  
15 Workup for transplant and VAD?

16 A. Yes.

17 Q. Signed by you?

18 A. Yes.

19 Q. What was it about this intraaortic balloon  
20 placement in October of 2007 that was now having you do  
21 the actual workup for a transplant and a VAD?

22 A. It may be that the hemodynamics justified it at  
23 that time. I just don't remember.

24 Q. Okay. Well, is this sort of long-term planning  
25 because you know that she's got to get listed and then

Reynolds Delgado, M.D.

May 25, 2011

Page 286

1 wait for a heart?

2 A. Yes.

3 Q. What is the average waiting time for a heart  
4 once you are listed and in status 1A?

5 A. It is -- those kind of statistics aren't kept  
6 because they're -- they're not very meaningful on an  
7 individual patient basis. So, I don't know.

8 Q. Are they kept for 1-Bs?

9 A. No, not for any.

10 Q. This is Exhibit 32. It's a printout of the  
11 Texas Heart Institute website. I think it was just  
12 printed last week. I believe I may have asked my staff  
13 to use the way-back machine to go back to the 2008  
14 website, but I'll leave that discussion for another day.  
15 Do you ever look at this Texas Heart website?

16 A. Not very often.

17 Q. All right. Into the first paragraph, it says  
18 (Reading): Today heart transplantation provides hope  
19 for a select group of patients who would otherwise die  
20 of heart failure.

21 Do you see that?

22 A. Yes.

23 Q. Do you agree with it?

24 A. Yes.

25 Q. Who writes this for the website?

Reynolds Delgado, M.D.

May 25, 2011

Page 287

1 A. I'm not quite sure actually.

2 Q. Do they consult with the cardiologists and the  
3 cardiothoracic surgeons to make sure it's scientifically  
4 accurate?

5 A. Yeah. Probably somebody vetted it.

6 Q. Okay. And the last paragraph before "The First  
7 Step Toward Transplantation" section describes in lay  
8 terms the process which leads to the need for mechanical  
9 devices for transplant. Do you see that paragraph? It  
10 starts (Reading): As the heart problem gets worse, the  
11 heart grows weaker.

12 A. Yes.

13 Q. Do you agree with that?

14 A. I think it's an oversimplification written  
15 in -- in a lay terminology.

16 Q. But simple as it is, it's accurate?

17 A. Yes.

18 Q. Okay. Next page, there's three indented bullet  
19 points under the section called "The Law of Supply and  
20 Demand."

21 A. Yes.

22 Q. And this defines the status of 1A and 1B?

23 A. Yes.

24 Q. Do you agree with these descriptions of those  
25 status categories?



1 A. Also oversimplified, but generally accurate.

2 Q. Okay. And I assume, Dr. Delgado, that Mimi  
3 Vega was either in these conditions that are described  
4 in this website or approaching these conditions or you  
5 would not have been doing an active transplant and VAD  
6 workup; correct?

7 A. Right.

8 Q. So, let's talk about LVADs.

9 Why don't we take a break. It's going to be a  
10 long topic. So --

11 A. Sure.

12 (RECESS FROM 4:21 P.M. TO 4:29 P.M.)

13 Q. (BY MR. MORIARTY) So, I want to talk about  
14 LVADs. And I showed you this before, this Exhibit 30.  
15 This is a note in your writing here (Reading): Likely  
16 need -- will likely need LVAD but will try again with  
17 metolazone and Lasix.

18 Correct?

19 A. Yes.

20 Q. In other words, in November of '07, she's back  
21 in the hospital; and you're thinking more likely than  
22 not, she's going to need an LVAD; correct?

23 A. Yes.

24 Q. All right. So, Exhibit 33 is a different  
25 section of your Texas Heart website. This one is about

1 ventricular assist devices. The last one, I think, was  
2 about transplant.

3 A. Yes.

4 Q. Third paragraph, last sentence says (Reading):  
5 When medicines and pacemakers no longer help the heart,  
6 patients need a heart transplant or a mechanical pump.

7 Correct?

8 A. Yes.

9 Q. And then if you go back to Page 3 out of 5  
10 (Reading): V A D S, VADs, are used for three main  
11 reasons: To keep patients alive until a donor heart can  
12 be found for transplantation.

13 That's called bridge to transplant. That's  
14 one; correct?

15 A. Yes.

16 Q. Second one they mention here is (Reading): To  
17 let the heart rest so it can recover and regain some of  
18 its normal function, heart failure remission.

19 While Mimi Vega was on -- I'm sorry. Let me  
20 rephrase that.

21 Was the purpose of Mimi Rivera-Vega's LVAD  
22 bridge to transplant, or was it bridge to recovery?

23 A. I don't know.

24 Q. Okay. Well, I don't want to cut you off. But  
25 in November -- October and November of 2007, you were

1 working her up for VAD and transplant; correct?

2 A. Yes.

3 Q. All right. Did you think in October or  
4 November of 2007, it was likely she was going to need  
5 transplant?

6 A. Yes.

7 Q. All right. In other words, the long-term  
8 ability for her to remain alive on long-term milrinone  
9 was unlikely. So, it was more likely than not she was  
10 going to need a transplant, even looking forward in time  
11 from October, November, 2007; correct?

12 A. Those weren't the only two options.

13 Q. Okay. What were her other options?

14 A. The LVAD as a DT or as a --

15 Q. Destination therapy?

16 A. Destination therapy or as a bridge to recovery.

17 Q. Okay. So -- but you thought -- you thought  
18 transplant was more likely than not; but if she had  
19 recovered well on the LVAD, it could be destination  
20 therapy; is that correct?

21 A. Those two are separate.

22 Q. All right. Well --

23 A. Yes. One of those two is possible.

24 Q. Okay. Well, I thought I asked you -- was it --  
25 looking forward from October, November of 2007, was it

1 more likely she was going to need a transplant? I  
2 thought you said yes.

3 A. I may have misunderstood.

4 Q. Okay.

5 A. All of those were possibilities.

6 Q. All right. Well, let me make sure I  
7 understand. Let's just take milrinone as an option.  
8 Long term -- you knew, based on experience and  
9 literature, that it was unlikely she could survive even  
10 up to a year on milrinone IV; correct?

11 A. Yes.

12 Q. All right. So, at some point, she was going to  
13 need a VAD and/or a transplant; correct?

14 A. Correct.

15 Q. And was it more likely that ultimately she was  
16 going to need a transplant?

17 A. Impossible to know.

18 Q. All right. So, basically by working her up for  
19 a transplant and a VAD, you're keeping your options  
20 open?

21 A. Yes.

22 Q. All right. Handing you Exhibit 55. This is an  
23 article that you and Dr. Frazier wrote in 2003; correct?

24 A. Yes.

25 Q. And early in this, you say that (Reading):

1 Posttransplantation mortality and morbidity have  
2 improved little over the past decade.

3 Is that right?

4 A. Yes.

5 Q. Let's go to the Page 3,065 of this article.

6 Who are the best candidates for MCS, which is  
7 mechanical --

8 A. Circulatory support.

9 Q. Mechanical circulatory support.

10 (Reading): At present, the most appropriate  
11 candidates for MCS are patients who are facing imminent  
12 death from heart failure but who still have adequate end  
13 organ function.

14 Did I read that correctly?

15 A. Yes.

16 Q. Did you still agree with that in 2007?

17 A. Generally, yes.

18 Q. Okay. Down further in the next paragraph,  
19 first sentence (Reading): Currently, long-term MCS is  
20 indicated for patients with chronic heart failure whose  
21 hemodynamic status deteriorates despite maximal drug  
22 therapy and/or intraaortic balloon pump assistance.

23 Did you still agree with that in 2007?

24 A. Generally, yes.

25 Q. Okay. Then further in this paragraph

1 (Reading): MCS should be instituted before further end  
2 organ deterioration occurs.

3 Do you agree with that?

4 A. Yes.

5 Q. The next sentence says (Reading): The current  
6 practice of outpatient intravenous therapy with  
7 milrinone or dopamine does not improve survival, and the  
8 precipitous deterioration that frequently occurs in  
9 these patients limits the timely application of MCS and  
10 frequently will adversely affect its successful use.

11 Did I read that right?

12 A. Yes.

13 Q. Was that still true in 2007?

14 A. Yes.

15 Q. Okay. Let's look at Exhibit 58. Did you  
16 coauthor this article?

17 A. Yes.

18 Q. It's about IV milrinone and treatment of  
19 advanced CHF; correct?

20 A. Yes.

21 Q. And you were looking at 65 patients with severe  
22 CHF who were in the New York Heart Association Class IV  
23 function with ejection fractions less than 25 percent;  
24 correct?

25 A. Yes.

1 Q. And does that describe Mimi Vega at the end of  
2 2007, beginning of 2008, Class IV with a low ejection  
3 fraction --

4 A. Yes.

5 Q. -- refractory to oral medical therapy?

6 A. Yes.

7 Q. 16 of these patients died, didn't they?

8 A. Yes.

9 Q. 31 percent.

10 And in the text, the third sentence says  
11 (Reading): The annual mortality rate of patients who  
12 have NYHA functional Class IV CHF remains high.

13 MS. RUSNAK: One second. I'm sorry.

14 She --

15 MR. MORIARTY: I just wanted to finish the  
16 question.

17 MS. RUSNAK: Well, she's got his pager.

18 MR. MORIARTY: That's okay.

19 MS. RUSNAK: It could be urgent. So, do  
20 you mind letting him look?

21 MR. MORIARTY: No. Go ahead. I can  
22 repeat the question.

23 (RECESS FROM 4:40 P.M. TO 4:43 P.M.)

24 Q. (BY MR. MORIARTY) I'm going to repeat my  
25 question. We were talking about Exhibit 58. And I'm in

1 the text, the third sentence (Reading): The annual  
2 mortality rate of patients who have NYHA functional  
3 Class IV CHF remains high regardless of therapy with  
4 digitalis, ACE inhibitors, diuretics, or beta blockers.  
5 In a growing number of patients, symptoms of NYHA Class  
6 IV CHF persist despite maximal oral medical management.

7 Do you still agree with that?

8 A. Yes.

9 Q. Now, if you go back to the second page of this,  
10 which is Page 110 of the journal, second column, top,  
11 first full sentence says (Reading): All patients had  
12 been unresponsive to the maximum oral dosages of  
13 digitalis, diuretics, and ACE inhibitors and could not  
14 be weaned from milrinone while in the hospital.

15 Correct?

16 A. Yes.

17 Q. So, in this study all of the 65 patients had  
18 weaning attempts; right?

19 A. Yes.

20 Q. Okay. And then if you go to the last page of  
21 your article, Page 112, towards the bottom above the  
22 "Conclusion" section, it says (Reading): The 23 percent  
23 mortality rate observed in our series after nearly a  
24 year, et cetera.

25 That is the -- 80 percent of these patients



1 died; correct? I'm sorry. 23 percent died; right?

2 A. Yes.

3 Q. And then up above, first sentence of that same  
4 paragraph, it says (Reading): Intravenous milrinone  
5 therapy has been associated with QT -- those are  
6 capitalized -- small c -- interval prolongation.

7 Do you see that?

8 A. Yes.

9 Q. (Reading): This effect may explain increased  
10 mortality rates seen with the use of inotropic agents.

11 Do you see that?

12 A. Yes.

13 Q. Do you still agree with that?

14 A. Yes.

15 Q. And, in fact, in -- sorry I didn't mark this.  
16 We can, if need be -- in 2002, you published an article  
17 about prolonged QTc intervals and high BNP levels,  
18 didn't you?

19 A. Yes.

20 Q. Predicting mortality in patients with advanced  
21 heart failure; is that right?

22 A. Yes.

23 Q. Did you ever look at the QTc intervals and BNP  
24 levels for Maria -- Mimi Rivera-Vega in February of  
25 2008?

Reynolds Delgado, M.D.

May 25, 2011

Page 297

1 A. I don't remember.

2 Q. Well, let's assume that three of those  
3 measurements, QTc interval and an EKG taken close in  
4 time to a BNP level all met the criteria for your 2002  
5 article. Okay?

6 A. Yes.

7 Q. Did you find that it was a strong independent  
8 predictor of adverse outcome in patients with heart  
9 failure?

10 A. Yes.

11 Q. And have you updated this study?

12 A. No.

13 Q. Is it still a strong independent predictor of  
14 adverse outcomes in patients with advanced heart  
15 failure?

16 A. Yes.

17 Q. Why?

18 A. Those two are markers of severity of heart  
19 failure, and using them together just strengthens the  
20 argument.

21 Q. Does digoxin lengthen QTc intervals?

22 A. Not that I know of.

23 Q. Does digoxin increase BNP levels?

24 A. No.

25 Q. There's an informed consent document for left

1 ventricular assist devices; is that correct?

2 A. Yes.

3 Q. Do you know whether the cardiology section had  
4 any input to the drafting of the LVAD informed consent  
5 document?

6 A. I don't know.

7 Q. How many different potential causes of LVAD  
8 failure are there?

9 A. Many.

10 Q. Some are related to the human body in which the  
11 LVAD is implanted; correct?

12 A. Yes.

13 Q. And some are related to the mechanical device  
14 itself; correct?

15 A. Correct.

16 Q. Following the placement of Mimi Vega's LVAD in  
17 February of 2008, she was still getting digoxin beta  
18 blockers and ACE inhibitors. Why?

19 A. We routinely do that for those patients that  
20 have the recovery, the remission. We believe it helps  
21 promote that.

22 Q. It's not that they have it. They don't have  
23 the recovery and remission. You believe that the drugs  
24 promote recovery and remission?

25 A. Correct.

Reynolds Delgado, M.D.

May 25, 2011

Page 299

1 Q. All right. Is there any published trials that  
2 prove that?

3 A. No.

4 Q. So, Texas Heart has been part of the  
5 development of the Jarvik heart -- Jarvik 2000 since  
6 1988; is that right?

7 A. Yes.

8 Q. And in 2002, you were part of a team of  
9 authors, along with Robert Jarvik himself, and  
10 Dr. Frazier, on a study, Exhibit 35 I've made this, the  
11 "Initial Clinical Experience With the Jarvik 2000";  
12 correct?

13 A. Yes.

14 Q. And there were -- you used the device in ten  
15 transplant candidates; is that right?

16 A. Yes.

17 Q. And three died during the support phase; is  
18 that right?

19 A. Yes.

20 Q. And according to the article, at 2857, it says  
21 (Reading): Two of the deaths were from ventricular  
22 ectopia. One was due to ARDS secondary to coagulopathy  
23 and significant blood transfusion.

24 Is that right?

25 A. Yes.

Reynolds Delgado, M.D.

May 25, 2011

Page 300

1 Q. You have published other articles about these,  
2 have you not?

3 A. Yes.

4 Q. Jarvik 2000s?

5 A. Yes.

6 Q. So, for example, Exhibit 34 -- I don't know if  
7 this is the same one I marked or showed you earlier.  
8 You co-authored this with Dr. Frazier and Dr. Conti;  
9 correct?

10 A. Yes.

11 Q. All right. And this was a study of 133  
12 patients with end stage heart failure who were on a  
13 waiting list for heart transplantation; correct?

14 A. Yes.

15 Q. And the survival rate during support was 75  
16 percent at six months; correct?

17 A. Yes.

18 Q. And 68 percent at 12 months; right?

19 A. Right.

20 Q. So, over time, patients had diminishing  
21 survival the longer they were on the device; is that  
22 right?

23 A. Yes.

24 Just to clarify, this is a different device  
25 than the Jarvik.

Reynolds Delgado, M.D.

May 25, 2011

Page 301

1 Q. Okay. Which device was this?

2 A. HeartMate II.

3 Q. Okay. Got it.

4 Was the HeartMate II at this time approved  
5 by -- fully approved by FDA for all uses?

6 A. Not at that time, no.

7 Q. All right. But this is a continuous flow pump,  
8 is it not?

9 A. Yes.

10 Q. Like the Jarvik 2000?

11 A. Yes.

12 Q. So, in the "Results" section on Page 888, first  
13 paragraph, it says (Reading): The primary cause of  
14 heart failure for the majority of patients was  
15 nonischemic cardiomyopathy.

16 Is that right?

17 A. Yes.

18 Q. And that's what Mimi Vega had, was nonischemic  
19 cardiomyopathy?

20 A. Yes.

21 Q. (Reading): Optimal oral medical therapy had  
22 failed in all patients; and all patients were receiving  
23 IV inotropic therapy, with 25 percent requiring more  
24 than one inotrope.

25 Did I read that correctly?

Reynolds Delgado, M.D.

May 25, 2011

Page 302

1 A. Yes.

2 Q. Does that also describe Mimi Vega, optimal oral  
3 medical therapy had failed; and she was receiving IV  
4 inotropes, as well as still getting digoxin; correct?

5 A. Yes. But the intent to that statement was a  
6 second IV inotrope.

7 Q. I got you.

8 Okay. So, when Mimi Vega had her Jarvik 2000  
9 placed, was she -- she was enrolled in a clinical trial,  
10 was she not?

11 A. Yes.

12 Q. Was it called The Pivotal Trial? I saw that  
13 phrase somewhere, "the pivotal trial"; and I didn't know  
14 whether that was the title of it or whether somebody was  
15 saying this was a pivotal trial and --

16 A. No.

17 Q. Okay. No, it wasn't called The Pivotal Trial?

18 A. Correct.

19 Q. Was that trial started in 2005? If you don't  
20 remember, just tell me you don't remember.

21 A. I don't think so, no.

22 Q. Is the trial closed?

23 A. I don't know that either.

24 Q. Do you know whether any results have been  
25 published?

Reynolds Delgado, M.D.

May 25, 2011

Page 303

1 A. No.

2 Q. Who would have been primarily responsible for  
3 delivering to Mimi the content of the informed consent?

4 A. The study coordinator.

5 Q. Is that a doctor?

6 A. No.

7 Q. What is the qualification of the study  
8 coordinator?

9 A. They are usually nurses and are trained in  
10 execution of clinical trials.

11 Q. Okay. And just so you understand, I don't mean  
12 getting -- the logistics of getting the document signed.  
13 I mean explaining the risks and complications. Is your  
14 answer still the same?

15 A. We have a PI responsible for that.

16 Q. Principal investigator?

17 A. Correct.

18 Q. Who would that have been for this trial?

19 A. Frazier.

20 Q. So, whether it was Dr. Frazier himself or  
21 another attending in that department or a fellow, it  
22 would have been surgeons giving the informed consent; is  
23 that correct?

24 A. Likely, yes.

25 Q. Not cardiology?



Reynolds Delgado, M.D.

May 25, 2011

Page 304

1 A. Correct.

2 Q. Not you?

3 A. Correct.

4 Q. Would you have had any discussions about the  
5 risks and complications of this with her?

6 A. Yes.

7 Q. All right. Do you know who contributed to  
8 write the content of this?

9 A. No.

10 Q. This is Exhibit 39, Mimi Rivera-Vega's executed  
11 informed consent for the clinical trial for the Jarvik  
12 2000; is that right?

13 A. Yes. It was likely Jarvik, his company.

14 Q. You mean it was likely Jarvik who wrote this?

15 A. Jarvik's company, Jarvik Heart, Inc.

16 Q. And why do you say that?

17 A. The study sponsor is generally responsible for  
18 writing the informed consents.

19 Q. What, if anything, is your affiliation with  
20 Jarvik Heart, Inc.?

21 A. None.

22 Q. You're not on the board?

23 A. No.

24 Q. Don't own any stock in it?

25 A. No.

1 Q. Okay. Do they give -- does Jarvik Heart, Inc.,  
2 give grants to institutions?

3 A. No.

4 Q. When was the last time you've read this?

5 A. Long time. We haven't done any Jarvik implants  
6 in years.

7 Q. At Texas Heart or you?

8 A. At Texas Heart.

9 Q. Why not?

10 A. They had a failure of one of the bearings in  
11 the device that led to a redesign; and, so, it's just  
12 been a long hiatus.

13 Q. What was the failure rate?

14 A. Well --

15 Q. You know what? That's a bad question because  
16 maybe they didn't wait around to see what the rate was.  
17 But, obviously, there was some signal in the clinical  
18 patterns that these were failing more frequently than  
19 they should. When did that happen?

20 A. Roughly in the 2008 time frame, somewhere in  
21 there.

22 Q. Do you know today whether Mimi Rivera-Vega's  
23 first Jarvik 2000 failed because of this bearing issue?

24 A. We don't know.

25 Q. Who did the post-explant device evaluations?

1           A.    We did to some extent.  The gross, we did; in  
2   other words, what you can see with the naked eye.

3           Q.    Sure.

4                    Could you see the bearings?

5           A.    Yes.

6           Q.    Do you know where the post-explant device  
7   evaluation would be documented?

8           A.    I don't.

9           Q.    Were they then sent back to Jarvik Heart or to  
10   an independent group for disassembly and further  
11   evaluation?

12          A.    Yes, to Jarvik.

13          Q.    Do you know when they were sent back to Jarvik  
14   whether they were tagged with any identifying  
15   information, whether it was patient name or implant date  
16   or serial number, data that could be matched to a  
17   patient's chart?

18          A.    I don't know actually.

19          Q.    Okay.

20          A.    The study pages had numbers, but I don't -- I  
21   don't know if the study allowed for the numbers to be  
22   correlated to patient identifier information.

23          Q.    All right.  At Page 6 of 9 in Exhibit 39, it  
24   says (Reading):  This device is not intended to be  
25   permanent.  It could fail suddenly and, therefore, must

1 be removed as soon as possible when a donor heart  
2 becomes available.

3 Do you agree with that?

4 A. Yes.

5 Q. Okay. So, by this point is it unlikely that  
6 her Jarvik 2000 was for destination therapy?

7 A. Not necessarily.

8 Q. Okay. Why was she enrolled in the trial of an  
9 experimental device as opposed to being given an  
10 approved device?

11 A. At the time the only approved device was a  
12 HeartMate XVE, and that was -- is generally considered  
13 inferior to the new generation of devices -- is inferior  
14 to the new generation of devices.

15 Q. Was it pulsatile flow?

16 A. Yes.

17 Q. I want to show you Exhibit 40. If those are  
18 cluttering up your space, you can just put them here,  
19 Doctor.

20 This is from the National Institutes of Health  
21 website, ClinicalTrials.gov. Have you ever seen this  
22 before?

23 A. No.

24 Q. It talks about the Jarvik 2000 Heart as a  
25 Bridge to Cardiac Transplantation - Pivotal Trial, and

Reynolds Delgado, M.D.

May 25, 2011

Page 308

1 it describes the purpose. Is this the trial in which  
2 she was enrolled?

3 A. I believe so, yes.

4 Q. All right. So, the purpose was to determine  
5 the safety and effectiveness of this Jarvik 2000 as  
6 bridge to transplant in end-stage heart failure;  
7 correct?

8 A. Yes.

9 Q. And the condition was end-stage heart failure;  
10 is that right?

11 A. Yes.

12 Q. So, on the second page of this where it says  
13 "Intervention Details," after where it says "Device," it  
14 says (Reading): The Jarvik 2000 heart implantation is  
15 intended for patients with end-stage heart failure who  
16 are approved heart transplant candidates.

17 Did I read that correctly?

18 A. Yes.

19 Q. Do you agree with that?

20 A. Yes.

21 Q. So, we know that this, by May 17th, was going  
22 to be removed. So, let me show you Exhibit 47. This is  
23 the operative note done by Igor Gregoric. I don't know  
24 if I pronounced that right.

25 A. Yes.

1 Q. It says (Reading): Left ventricular assist  
2 device failure.

3 That was the preoperative diagnosis; correct?

4 A. Yes.

5 Q. And do you know whether there was ever a  
6 determination by the surgeons or anyone else what the  
7 cause of this device failure was?

8 A. I don't remember.

9 Q. Is there anything in your own files to indicate  
10 that there was follow-up about what the cause of the  
11 device failure was?

12 A. I don't know. I could look.

13 Q. Where would I find information about when  
14 your -- you and your colleagues at St. Luke's and Texas  
15 Heart stopped implanting Jarvik 2000s?

16 A. The -- well, it would be the research. The  
17 research coordinator would have that info.

18 Q. Do you know who that is now?

19 A. I don't know who's assigned to this study right  
20 now.

21 Q. Would it be somebody -- I mean, is there a  
22 distinct research coordinator division --

23 A. Yes.

24 Q. -- or is this somebody working under the  
25 umbrella of Dr. Frazier?

Reynolds Delgado, M.D.

May 25, 2011

Page 310

1           A.    Yes.  There's a department, circulatory support  
2   department; and I suspect there's not anybody -- any  
3   person assigned to this right now since it's in an  
4   inactive state.

5           Q.    Okay.  Do you know whether it's active  
6   elsewhere?

7           A.    Yes.

8           Q.    Is it?

9           A.    Yes.

10          Q.    Someone used -- is recycling paper.  Sorry.  
11   But the back of this is something that I'm not  
12   privileged --

13          A.    What?

14          Q.    That's not supposed to be on the back of  
15   Exhibit 46.

16          A.    Okay.

17          Q.    It's just a service page.

18                Is Exhibit 46 a procedure note by you for  
19   another left heart catheterization and other procedures  
20   on May 23rd, 2008?

21          A.    Yes.

22          Q.    And this is while she has her second device; is  
23   that correct?

24          A.    Yes.

25          Q.    So, Exhibit 47 was the removal May 17th of her

Reynolds Delgado, M.D.

May 25, 2011

Page 311

1 first device; and they put in another one, didn't they?

2 A. Yes.

3 Q. They put in another Jarvik 2000?

4 A. Correct.

5 Q. So, this evaluation in Exhibit 46 on May 23rd  
6 is you evaluating LVAD failure and CHF with her second  
7 device; is that right?

8 A. Yes.

9 Q. (Reading): Findings: She had deranged  
10 hemodynamics of heart failure.

11 Correct?

12 A. Yes.

13 Q. And it didn't improve as much as you would  
14 expect when you cranked up the pump speed; right?

15 A. Yes.

16 Q. (Reading): The reasons for continued heart  
17 failure are unclear but could involve a stenosis at the  
18 inflow to the LVAD or a problem with the controller.

19 Is that right?

20 A. Yes.

21 Q. Now, ultimately, this pump was explanted, as  
22 well; is that correct?

23 A. Yes.

24 Q. Do you know what the cause of this -- do you  
25 have an opinion, to a probability, as to what was the



1 most likely cause of this second pump's failure?

2 A. I just don't know.

3 Q. Do you know -- who would be the best person to  
4 ask?

5 A. Jarvik.

6 Q. Or a surgeon? I mean, would Dr. Frazier have  
7 any better opinion on this than you?

8 A. He might.

9 Q. Okay. Do you know anything more about the  
10 device -- post-explant device evaluation for this second  
11 device?

12 A. No.

13 Q. Exhibit 48 is the actual operative report by  
14 Dr. Frazier for the removal of the second device and the  
15 placement of a new one, is it not?

16 A. Yes.

17 Q. And in this case he took out the second Jarvik  
18 2000, put in a HeartMate II, and a secondary device  
19 called a Centrimag; right?

20 A. Yes.

21 Q. Does his operative note give you any more  
22 indication of what the cause of the device failure was?

23 A. No.

24 Q. I asked you a little bit about the concept of  
25 this exhibit in your first deposition, but we didn't

1 have this as an exhibit at the time. So, this is  
2 Exhibit 45. It's a letter dated February 19th, 2008,  
3 isn't it?

4 A. Yes.

5 Q. Is it to you?

6 A. Yes.

7 Q. Is it from an infectious disease consult?

8 A. Yes.

9 Q. And in the second sentence, does he refer to  
10 Mimi Vega as having end-stage postpartum cardiomyopathy?

11 A. Yes.

12 Q. Is that a conclusion that he would have  
13 received from you or from the surgeons or gleaned it  
14 from the chart?

15 A. Any or all.

16 Q. Did you ever chart any disagreement of his  
17 assessment that that was her condition?

18 A. No.

19 Q. Do you agree that that's a way to characterize  
20 her condition as of February, or even January, 2008?

21 A. No.

22 Q. Wasn't end-stage heart failure the entry  
23 criteria for the implantation of a Jarvik 2000?

24 A. Yes.

25 Q. So, why do you disagree with that statement?

Reynolds Delgado, M.D.

May 25, 2011

Page 314

1 A. I don't use the terminology.

2 Q. Okay. Any other reason?

3 A. No.

4 Q. If it is the entry criteria for the study on  
5 the NIH website, what's wrong with the terminology that  
6 you won't use it?

7 A. It's old terminology and does not provide  
8 anything of value, and it can be confusing.

9 Q. I'm showing you Exhibit 29. This is a note  
10 from GHC, which, I believe, is the home health care  
11 agency that was going to be taking care of Mrs. Vega's  
12 IV milrinone. Okay? On the first page, "Homebound  
13 Status" on the right side above the checkmarks. Excuse  
14 me for pointing, but it's in there.

15 A. Yes.

16 Q. Does that say (Reading): Fatigue, shortness of  
17 breath, and decreased endurance?

18 A. Yes.

19 Q. But she was homebound at this point; right?

20 A. I don't remember specifically.

21 Q. All right. Go to the second page, please.  
22 Left column, very bottom, there's a comment. It says  
23 that (Reading): Her condition is related to end-stage  
24 CHF.

25 Do you see that?

Reynolds Delgado, M.D.

May 25, 2011

Page 315

1 A. Yes.

2 Q. Where would somebody like the GHC staff, who, I  
3 believe, are nurses, get that?

4 A. I don't know.

5 Q. Is it generally thought that in order to  
6 qualify for IV home milrinone, you have to have at least  
7 the label of "end-stage" given to you by someone?

8 A. I don't know. I don't think so.

9 Q. I'm showing you Exhibit 43.

10 Do you have something you want to add about the  
11 last exhibit?

12 A. No.

13 Q. Okay. I'm showing you Exhibit 43. Is this a  
14 letter, February 5th, 2008, from the Clinical Director  
15 of Transplant Services?

16 A. Yes.

17 Q. And in the section after her diagnosis, it says  
18 (Reading): Mrs. Vega is a medically acceptable  
19 candidate for heart transplant due to end-stage cardiac  
20 disease secondary to postpartum cardiomyopathy.

21 Do you see that?

22 A. Yes.

23 Q. In order to be listed on the transplant, does  
24 somebody have to diagnose you with end-stage cardiac  
25 disease?

1 A. No, not necessarily.

2 Q. What is Whitson Ethridge's specialty?

3 A. He's a renal specialist.

4 Q. Do you know where he got the label of  
5 "end-stage" as it applies to Mimi Vega?

6 A. No.

7 Q. Did you ever tell them she was not end-stage?

8 A. No.

9 Q. Exhibit 44 is an operative note from  
10 Dr. Frazier for the implantation of Mrs. Vega's first  
11 Jarvik 2000. Am I correct about that?

12 A. Yes.

13 Q. What were the pre and postoperative diagnoses  
14 that Dr. Frazier and his team charted?

15 A. End-stage heart failure.

16 Q. Can end-stage nonischemic cardiomyopathy be a  
17 cause of cardiogenic shock?

18 A. It's better said that it can lead to  
19 cardiogenic shock.

20 Q. Why -- why is it better said that it can lead  
21 to as opposed to cause?

22 A. Because someone may have cardiomyopathy and  
23 develop cardiogenic shock, but the cardiomyopathy isn't  
24 the cause of developing cardiogenic shock.

25 Q. Okay. Is cardiogenic shock associated with a

Reynolds Delgado, M.D.

May 25, 2011

Page 317

1 poor prognosis?

2 A. Yes.

3 Q. Mortality rates, 50 to 80 percent in some  
4 series?

5 A. Yes.

6 Q. Do you agree that to improve outcomes,  
7 cardiogenic shock needs to be recognized early in its  
8 course and its cause needs to be diagnosed rapidly?

9 A. Yes.

10 Q. Interesting. I'm holding an article by  
11 Dr. Topalian, Ginsberg, and Joe Parrillo. Do you know  
12 any of them?

13 A. No.

14 Q. They're at the Cooper Heart Institute in  
15 New Jersey. They're talking about etiology. And it  
16 says (Reading): Many conditions may lead to cardiogenic  
17 shock.

18 And then the table says "Causes of Cardiogenic  
19 Shock." So, one uses your term; and one uses mine. Do  
20 you agree that left ventricular failure due to extensive  
21 acute MI is the most common cause?

22 A. Yes.

23 Q. But end-stage cardiomyopathy can either lead to  
24 or, put another way, cause cardiogenic shock; is that  
25 right?

1 MS. RUSNAK: Objection, form.

2 A. Well, like I said, I think "lead to" is the  
3 better --

4 Q. (BY MR. MORIARTY) Okay. That's fine.

5 Why is it important to understand the cause of  
6 the cardiogenic shock?

7 A. Because it may be something simple that can be  
8 easily reversed.

9 Q. So, for example, if somebody thought that  
10 digoxin excess was leading to cardiogenic shock, one  
11 thing you could do would be discontinue the digoxin;  
12 correct?

13 A. Yes.

14 Q. And if it was volume overload from dietary or  
15 medical indiscretion, you could provide inotropic  
16 support and diurese the patient; and that might prevent  
17 the cause of cardiogenic shock; is that true?

18 A. It's not common for volume overload to cause  
19 cardiogenic shock.

20 Q. Lead to?

21 A. Or even lead to.

22 Q. Okay.

23 A. But that's -- yeah, it's different.

24 Q. All right. Now, earlier in one of the exhibits  
25 of your articles, you referred to these ACC/AHA

1 guidelines. I want to talk about these just a little  
2 bit. That's Exhibit 37. Is that what -- this is the --  
3 I think the summary article of the guidelines; correct?

4 A. Yes.

5 Q. The actual guidelines are a lot thicker.

6 A. Yes.

7 Q. Have these been updated since 2005?

8 A. I don't know, to be honest.

9 Q. Are you still a member of the ACC?

10 A. Yes.

11 Q. Okay. So, I want to make sure I understand the  
12 way the writing groups do this. Let's go to Page 1827.  
13 The numbers are in the upper right-hand corner of the  
14 page.

15 MS. RUSNAK: What was that?

16 MR. MORIARTY: 1827. It's about the  
17 fourth page of this thing.

18 Q. (BY MR. MORIARTY) Left column, last full  
19 paragraph, they're talking about in formulating the  
20 documents that came up with this new approach to  
21 classifying heart failure. Do you see where I am?

22 A. Yes.

23 Q. And at the bottom of the page, they say what  
24 Stage C is, which is (Reading): Patients with current  
25 or past symptoms of heart failure associated with



1 underlying structural heart disease.

2 Do you see that?

3 A. Yes.

4 Q. Do you agree with that, that that is a  
5 nomenclature that's used?

6 A. Yes.

7 Q. You've used it in some of your own articles?

8 A. Yes.

9 Q. Then they describe Stage D (Reading): Patients  
10 with truly refractory HF who might be eligible for  
11 specialized, advanced treatment strategies such as  
12 mechanical circulatory support, continuous inotropic  
13 infusions, cardiac transplant, or other innovative and  
14 experimental procedures.

15 Correct?

16 A. Yes.

17 Q. As of October, November, 2007, was Mimi  
18 Rivera-Vega more likely than not a Stage D categorized  
19 patient?

20 A. Yes.

21 Q. All right. Now, on the bottom of the  
22 right-hand column, they have these things called  
23 "Classification of Recommendations." And I don't want  
24 to go through these, but is the bottom line that they  
25 are -- what they're doing is breaking out sort of the --

1 a way to classify the scientific strength of a  
2 recommendation?

3 A. Yes.

4 Q. All right. So, where there's agreement and  
5 scientific proof, it gets the highest classification;  
6 right?

7 A. Correct.

8 Q. And if there's some evidence or it's  
9 controversial, it's more likely going to slide down the  
10 scale; is that right?

11 A. Yes.

12 Q. Okay. So, let's go to Page 1837. The topic --  
13 I'm sorry. If you go back one more page, they're  
14 talking about patients with -- in Stage C and what the  
15 recommendations are. Do you see that?

16 A. Yes.

17 Q. That's the section that leads into the next  
18 page, 1837.

19 A. Yes.

20 Q. (Reading): Class III, Item 3 is the long-term  
21 use of an infusion of a positive inotropic drug may be  
22 harmful and is not recommended for patients with current  
23 or prior symptoms of HF and reduced LVEF, except as  
24 palliation for patients with end-stage disease who  
25 cannot be stabilized with medical treatment.

Reynolds Delgado, M.D.

May 25, 2011

Page 322

1 Right?

2 A. I'm sorry. Are you on 37?

3 Q. I'm on 1837.

4 A. Okay.

5 Q. And it's a lot of gibberish, to some extent;  
6 but basically what they're saying is that you shouldn't  
7 put heart failure C patients on long-term milrinone;  
8 correct?

9 A. Yes.

10 Q. Okay. That's reserved for stage D patients;  
11 right?

12 A. Yes.

13 Q. So, if we go to the section about Stage D  
14 patients on Page 1844 -- and this page number will be in  
15 your upper left. Are you there?

16 A. Yes.

17 Q. (Reading): Class I, which is the highest  
18 recommendation, includes referral for transplant in  
19 potentially eligible patients.

20 Is that right?

21 A. Yes.

22 Q. (Reading): Class IIA, a slightly lesser  
23 scientific recommendation, consideration of an LV assist  
24 device as permanent or destination therapy is  
25 reasonable.

Reynolds Delgado, M.D.

May 25, 2011

Page 323

1 Correct?

2 A. Yes.

3 Q. And then Class III -- I'm sorry. I'll withdraw  
4 that question.

5 Stage -- or Class IIB, Item 3, is where they  
6 have the recommendation about continuous IV infusions of  
7 inotropes; correct?

8 A. Yes.

9 Q. All right. Under the paragraph numbered 2,  
10 which says "Intravenous Peripheral Vasodilators and  
11 Positive Inotropic Agents," does that describe  
12 milrinone, by the way?

13 A. Yes.

14 Q. It says about halfway through that paragraph  
15 (Reading): The decision to continue intravenous  
16 infusions at home should not be made until all  
17 alternative attempts to achieve stability have failed  
18 repeatedly because such an approach can present a major  
19 burden to the family and health services and may  
20 ultimately increase the risk of death.

21 Do you see that?

22 A. Yes.

23 Q. Did I read it correctly?

24 A. Yes.

25 Q. Do you agree with it?

1 A. Depends on which population of patients you're  
2 talking about.

3 Q. Well, this is Stage D refractory end-stage  
4 heart failure patients like Mimi Rivera-Vega.

5 A. The distinction has to be made whether they're  
6 transplant eligible or not.

7 Q. Well --

8 A. Whether it's used as a BTT or palliative care.

9 Q. Okay. But regardless of whether it's used as  
10 BTT or palliative care, should all alternative attempts  
11 to achieve stability have failed before you try the IV  
12 milrinone?

13 A. No.

14 Q. Did these guidelines, Exhibit 37, form the  
15 basis for the treatment and recommendations that you  
16 made in your book chapter, Exhibit 52? And just to give  
17 you the shortcut, first page of this chapter, right  
18 column, halfway through the second full paragraph.

19 A. I'm sorry. What's that question?

20 Q. It says (Reading): These guidelines form the  
21 basis for treatment and recommendations made in this  
22 chapter referring to the AHA/ACC guidelines.

23 Correct?

24 A. Yes.

25 Q. Okay. Now, at the time you wrote the chapter,

1 the 2005 ones hadn't been published yet; correct?

2 A. Yes.

3 Q. So, what you're referring to as guiding -- the  
4 guidelines that form the basis for your chapter were the  
5 predecessors to Exhibit 37?

6 A. Correct.

7 Q. Okay. Let's go to Page 560 of your chapter,  
8 right-hand column, last sentence in the paragraph before  
9 the beta blocker section.

10 A. Yes.

11 Q. It says (Reading): If amiodarone is used for  
12 this purpose, it is important to reduce the dose of  
13 digoxin or monitor its levels closely since amiodarone  
14 reduces renal and nonrenal clearance of digoxin, thereby  
15 increasing serum concentrations.

16 Did I read that correctly?

17 A. Yes.

18 Q. You still agree with that?

19 A. Yes.

20 Q. When Mimi Vega was in the hospital in January  
21 of 2008, she was on -- was she on the .250-milligram  
22 dose?

23 A. I don't remember.

24 Q. Well, let's assume she was. When you started  
25 her on -- or prescribed amiodarone on discharge on the

Reynolds Delgado, M.D.

May 25, 2011

Page 326

1 25th, why didn't you reduce the dose to .125?

2 A. I don't remember.

3 Q. Have you published articles in the journal  
4 "Circulation"?

5 A. Yes.

6 Q. Had you ever diagnosed Mimi Vega with renal  
7 insufficiency prior to February, 2008?

8 A. I don't know.

9 Q. Did you diagnose her with renal insufficiency  
10 in February of 2008?

11 A. I don't remember.

12 Q. If she was diagnosed with renal insufficiency,  
13 should it be charted in the medical records?

14 A. Yes.

15 Q. And her BUNs, creatinines, or glomerular  
16 filtration rate estimates should reflect that; correct?

17 A. Yes.

18 Q. If her baseline renal function was intact and  
19 normal, would the ventricular assist device improve her  
20 renal clearance of digoxin to any appreciable degree?

21 A. No one knows.

22 Q. If you are conducting a clinical trial and you  
23 suspect that a patient has digoxin toxicity, do you keep  
24 them on the drug?

25 A. No.

1 Q. If you suspect that digoxin is causing harm, do  
2 you keep the patient on the drug?

3 A. No.

4 Q. I asked you before whether you were aware of  
5 any data about serum levels -- serum digoxin levels  
6 expected at certain doses. What I've handed you is  
7 Exhibit 62, which was written by Mihai Gheorghiade and  
8 Kirkwood Adams. Do you see that?

9 A. Yes.

10 Q. Two of the same authors that wrote Exhibit  
11 12 -- or Exhibit 17; correct?

12 A. Yes.

13 Q. If you go to Page 2961, the very end of the  
14 first column and the top of the second column says  
15 (Reading): Additional data from the DIG trial suggests  
16 that in patients with normal renal function who are not  
17 receiving medications that tend to increase SDC, a dose  
18 of .125 milligrams daily will result in SDC of  
19 approximately .8 nanograms per milliliter.

20 Did I read that correctly?

21 A. Yes.

22 Q. Now, what would you expect the patient's serum  
23 digoxin concentration to be if they were receiving .25  
24 milligrams daily and had normal renal function and no  
25 medications that tend to increase digoxin?



1           A.     It's very variable, depending on their age,  
2     their weight. I can't really predict.

3           Q.     Do you have an opinion, to a reasonable degree  
4     of probability, about a 35-year-old woman who weighs  
5     about 220 pounds?

6           A.     Yes.

7           Q.     In your opinion, to a probability, what would a  
8     daily dose of .25 milligrams yield in that patient as an  
9     SDC?

10          A.     It should yield a -- a normal level roughly.

11          Q.     Under 2?

12          A.     Yes.

13          Q.     But it could be as high as 1.2?

14          A.     It's possible, yes.

15          Q.     Okay. And, of course, if a patient was on a  
16     medication that could increase serum levels, then it  
17     could be higher?

18          A.     Correct.

19          Q.     I want to hand you Exhibit 41, which is  
20     Wal-Mart pharmacy prescription records from Mimi Vega  
21     from January of 2008. And it shows that on January  
22     13th -- this is the second to last entry on the page --  
23     January 13th, 2008, you were the prescribing physician  
24     for Mimi Vega to get .25 milligrams of digoxin, 30  
25     tablets. Do you see that?

1 A. Yes.

2 Q. Now, having seen that, does this jar your  
3 memory as to why you increased her dosage level at this  
4 point?

5 MS. RUSNAK: Objection, form.

6 MR. MORIARTY: I'm not sure what's the  
7 matter with the form of that.

8 Q. (BY MR. MORIARTY) But earlier you told me you  
9 didn't remember why you've bumped it up. I've now shown  
10 you the actual document that indicates that you did.  
11 I'm just wondering if this refreshes your memory as to  
12 why.

13 MS. RUSNAK: Objection, form.

14 A. No. I'm not sure when I wrote that  
15 prescription based on this. It could have been 9/07.

16 Q. (BY MR. MORIARTY) Well, does this indicate that  
17 she refilled it on January 13th?

18 A. I don't know how to read that.

19 Q. So, if Mimi Vega was taking her digoxin as  
20 prescribed with this dose from January 13th through the  
21 22nd when she was admitted to St. Luke's Hospital with  
22 an exacerbation of heart failure, it wouldn't be  
23 surprising if her serum level was up at 1.2, would it?

24 A. Yes, that would be surprising, given her age  
25 and her size.

1 Q. What -- why would her age and her size make a  
2 level of 1.2 surprising?

3 A. Well, it would. It just would. Usually a  
4 person of her age and size would have a lower level with  
5 that dose.

6 Q. Why? What is it about her age and her size,  
7 assuming she has normal renal function?

8 A. Those are two big determinates of -- of the  
9 effect of the digoxin in -- in -- on the blood levels  
10 basically.

11 Q. Did anybody -- you or any of your staff, during  
12 the January 22nd to 25th hospitalization, chart that  
13 they were surprised by the serum level of 1.2?

14 A. Not that I remember.

15 Q. Wasn't she kept on .25 digoxin during that  
16 hospitalization?

17 A. I don't specifically remember.

18 Q. Wasn't she kept on it and discharged on it?

19 A. Yes.

20 Q. Along with amiodarone?

21 A. Yes.

22 Q. She wasn't diagnosed with cardiogenic shock  
23 during the hospitalization of January 22 through 25,  
24 2008, was she?

25 A. I don't remember.

Reynolds Delgado, M.D.

May 25, 2011

Page 331

1 Q. Okay. This is your discharge summary from that  
2 admission. Did anybody diagnose or chart cardiogenic  
3 shock?

4 A. No.

5 Q. Does it say what her admitting medications  
6 were?

7 A. No.

8 Q. Was she on any medications -- well, I'll  
9 withdraw that.

10 Don't the dosing guidelines for digoxin say to  
11 dose to lean body mass, not fat?

12 A. I'm not sure.

13 Q. Digoxin isn't preferentially distributed to  
14 adipose tissue, is it?

15 A. I don't know.

16 Q. I'll come back to that.

17 Now, just so I understand your opinion today,  
18 in your opinion today, were you correct about her  
19 diagnosis in January of 2008?

20 A. Yes.

21 Q. And in your opinion, was she treated  
22 appropriately for your diagnosis?

23 A. Yes.

24 Q. But if, in fact, digoxin excess was the cause  
25 of that heart failure exacerbation, are you saying that

1 in retrospect, your diagnosis and treatment was wrong?

2 A. I'm not sure.

3 Q. You're not sure of the answer, or you're not --

4 A. Right.

5 Q. -- sure you understand my question?

6 A. Either.

7 Q. Okay. Exhibit 23 is your discharge summary

8 from the admission of January 22nd through 25th, 2008.

9 Okay? You and your team were taking care of her during  
10 this heart failure exacerbation issue; correct?

11 A. Yes.

12 Q. Okay. And nowhere in here do you chart -- or  
13 anyplace else in the chart, for that matter -- digoxin  
14 excess as the cause of her serum level of 1.2 or heart  
15 failure exacerbation or anything else. Okay? What you  
16 did was you diagnosed her with volume overload, treated  
17 her with inotropic agents, and diuretics -- diuretics, I  
18 should say, and relieved her of her exacerbation of  
19 congestive heart failure; correct?

20 A. Correct.

21 Q. All right. So, at the time what you've now  
22 told me is that these diagnoses and treatments were  
23 correct; right?

24 A. Yes.

25 Q. But you have opinions that you've developed

1 retrospectively, long after these events occurred, that  
2 digoxin, in fact, was the cause of this admission and  
3 her falling off the cliff. Okay?

4 A. Yes.

5 Q. You've testified to that. You've written that  
6 in your report; correct?

7 A. Yes.

8 Q. Now, perhaps this admission isn't part of her  
9 falling off the cliff. I thought it was, based on the  
10 serum level of 1.2. Am I correct about that?

11 A. It was part of it, yes.

12 Q. Okay. So, are you telling us now, in  
13 hindsight, that your diagnosis and treatment was wrong?

14 A. No.

15 Q. Why wasn't it wrong even in hindsight?

16 A. The exacerbation and volume overload was the  
17 problem that prompted that admission and was diagnosed  
18 and treated properly at that admission.

19 Q. Are you done with your answer?

20 A. Yes.

21 Q. But you didn't discontinue digoxin; and then  
22 amiodarone was prescribed, which can drive levels up,  
23 which would be inappropriate treatment for somebody with  
24 digoxin excess; correct?

25 A. Depends on the dose.

1 Q. Well, if a patient comes in and you believe  
2 that they have digoxin excess or digoxin toxicity and  
3 you give them .25 milligrams -- and it's a woman -- and  
4 amiodarone, that's not appropriate treatment, is it?

5 A. Depends on the dose, particularly the  
6 amiodarone.

7 Q. So, you're saying there could be circumstances  
8 where giving -- continuing to give digoxin to a patient  
9 who is being harmed by it is appropriate treatment?

10 A. No.

11 Q. Does alprazolam increase DIG levels?

12 A. I don't know. I'll have to look it up.

13 Q. Amiodarone does, though, doesn't it?

14 A. Depends on the level.

15 Q. Depends on the level --

16 A. The dose.

17 Q. -- of the amiodarone?

18 A. Yes.

19 Q. Well, in the article or in your book, I think,  
20 what I read you from before, do you say that it depends  
21 on the level of amiodarone as to whether you reduce the  
22 digoxin dose?

23 A. I don't think it specifically says that in the  
24 book.

25 Q. If digoxin was the problem for Mimi Vega

1 January 22nd through 25th, 2008, would you have expected  
2 her to improve quickly on Lasix and milrinone while  
3 being kept on .25 digoxin?

4 A. Yes.

5 Q. Why?

6 A. They're separate issues.

7 Q. Well, doesn't digoxin continue to have its, in  
8 your opinion, deleterious effect on the heart?

9 A. Yes.

10 Q. But the deleterious effect is being masked by  
11 their clinical improvement because of the Lasix?

12 A. No.

13 Q. How could the patient who's being harmed by  
14 digoxin improve quickly with Lasix and milrinone if you  
15 keep them on digoxin?

16 A. Just a clarification, was it nesiritide we used  
17 then or milrinone? I don't remember.

18 Q. It's nesiritide.

19 A. Yes. Those drugs improved the volume  
20 overloaded state, which has nothing to do with the  
21 deleterious effects of the amiodarone -- I mean the --  
22 sorry -- the excessive digoxin.

23 Q. But wouldn't she continue to have -- if digoxin  
24 was, in fact, either causing clinical signs or symptoms  
25 or EKG changes or heart failure, worsening heart



1 failure, it would continue to do that, wouldn't it?

2 A. Digoxin continued to cause worsening heart  
3 failure culminating in the need for the LVAD shortly  
4 thereafter.

5 Q. But when you discharged her, she wasn't in  
6 worsening heart failure on January 25th, was she?

7 A. I don't -- I don't think I knew at that time.

8 Q. Well, would you have discharged somebody from  
9 the hospital or allowed your fellows or residents to  
10 discharge somebody from the hospital who was in --  
11 continued to be in worsening heart failure?

12 A. Not if we knew.

13 Q. And at that point, based on all the staff who  
14 was looking at her and the tests that were available to  
15 you, no one thought she was in worsening heart  
16 failure -- correct -- at the time of discharge?

17 A. We had no way of knowing at that time, correct.  
18 No one had no way of knowing.

19 Q. Well, you had clinical acumen, lab studies  
20 available, EKGs available, echocardiograms available.  
21 You had all of this available at this hospital to know  
22 whether she was in worsening heart failure; correct?

23 A. Those are necessary but not sufficient  
24 basically.

25 Q. Well, what would you have needed?

1 A. Hemodynamics.

2 Q. Well, that was available, because you did it at  
3 the next admission at the same hospital; correct?

4 A. It wasn't available at the time.

5 Q. An intraaortic balloon pump was not available  
6 on January 22nd?

7 A. No, no. The decision-making based on that data  
8 wasn't available at the time.

9 Q. The bottom line is that nobody was clinically  
10 suspicious that she was in worsening heart failure at  
11 the time of discharge; correct?

12 A. That's right. That's the basic trick here.

13 Q. Do you need to get a phone call?

14 A. No.

15 Q. I'm looking for Exhibit 50. I can't seem to  
16 find any of it.

17 A. Here it is. I got it.

18 Q. Okay. In your report at Page 19, you render an  
19 opinion that (Reading): Ms. Vega's death was caused by  
20 digoxin toxicity brought on by her ingestion of Digitek  
21 which has been shown to have increased pill dosages.

22 Okay. What is the basis for your opinion that  
23 Digitek has been shown to have increased pill dosages?

24 A. I don't remember the specific piece of data I  
25 was drawing from there.

1 Q. Well, what kind of data was it? Was it from  
2 the FDA?

3 A. It may have been.

4 Q. Well, where else may it have been from?

5 A. I don't remember specifically.

6 Q. Is it based just on the fact of -- that there  
7 was a recall?

8 A. Like I said, I don't remember specifically.

9 Q. Well, I don't mean to be a pain in the neck;  
10 but I am entitled to know the basis of your opinions.  
11 And that is a pretty important one. Is there something  
12 in your stack of materials here that you reviewed to  
13 form these opinions that would tell you the basis of  
14 your statement that Digitek has been shown to have  
15 increased pill dosages?

16 A. I don't know.

17 Q. On the next page, Page 20, it says (Reading):  
18 FDA found improperly manufactured Digitek products at  
19 the Actavis facility that had twice the appropriate  
20 level of the active ingredient that were released to the  
21 marketplace.

22 What's the basis for that opinion?

23 A. I don't remember specifically.

24 Q. Dr. Delgado, I can tell you that I have spent  
25 countless hours looking at FDA documents and questioning

1 the pharmaceutical witnesses who were hired by the  
2 plaintiffs in this litigation to talk about whether  
3 there was evidence of improperly manufactured Digitek at  
4 twice the appropriate level of active ingredient. Would  
5 you defer to the people who have read all the FDA  
6 documents and who have worked in the pharmaceutical  
7 business on these two opinions?

8 MS. RUSNAK: Objection, form.

9 A. Not necessarily.

10 Q. (BY MR. MORIARTY) Well, then please find in  
11 your materials -- we can take a break, and I can kind of  
12 reshuffle my notes here -- and find for me where in your  
13 material is the basis for these opinions that Digitek is  
14 shown to have increased pill dosages or that the FDA  
15 found Digitek with twice the appropriate level of the  
16 active ingredient that were released to the marketplace.  
17 Okay?

18 A. Yes.

19 (RECESS FROM 6:09 P.M. TO 6:24 P.M.)

20 Q. (BY MR. MORIARTY) Okay. My question was the  
21 basis of your statement in your report about basically  
22 Digitek with excessive doses being distributed to  
23 market.

24 A. The Exhibit 14 and 16 are press releases from  
25 Actavis that speak to this.

1 Q. Okay. Before I start asking you about Exhibits  
2 14 and 16, are these documents the sole basis for your  
3 opinion on this subject?

4 A. At the time I don't know if those were the sole  
5 basis.

6 Q. Okay. Well, let's look at 14, which is a press  
7 release; correct?

8 A. Yes.

9 Q. And it says -- again, I think we talked about  
10 this before -- (Reading): The recall is due to the  
11 possibility -- not the probability -- that tablets with  
12 double the appropriate thickness may have been  
13 commercially released.

14 Correct? So, they're saying it's possible that  
15 double-thick tablets were released; is that right?

16 A. Yes.

17 Q. It doesn't say probable or likely; correct?

18 A. Yes.

19 Q. And you've never seen a report of a  
20 double-thick tablet. I recall you telling me that;  
21 correct?

22 A. Yes.

23 Q. Do you know if any plaintiff in this entire  
24 litigation, of the thousands of claimants who sued, ever  
25 produced evidence of a double-thick tablet?

Reynolds Delgado, M.D.

May 25, 2011

Page 341

1 A. I don't know.

2 Q. Do you know whether a -- does it make a  
3 difference to you whether anybody ever found one?

4 MS. RUSNAK: Objection, form.

5 A. Not necessarily.

6 Q. (BY MR. MORIARTY) Do you know whether double  
7 thickness is a different pharmaceutical problem from  
8 normal sized with too much digoxin?

9 A. I don't know.

10 Q. Well, this doesn't -- this press release  
11 doesn't say that normal-sized digoxin with too much  
12 active pharmaceutical ingredient was implicated, does  
13 it?

14 A. No.

15 Q. Do you have any -- did you read Scottie Vega's  
16 deposition?

17 A. No.

18 Q. Do you know whether Scottie Vega ever noticed  
19 any difference in the size of his wife's Digitek  
20 tablets?

21 A. No.

22 Q. Do you know whether pharmacists who are  
23 counting out tablets and dispensing them into  
24 prescriptions would be able to detect double-thick  
25 tablets in prescriptions?

Reynolds Delgado, M.D.

May 25, 2011

Page 342

1 A. Unknown.

2 MR. MORIARTY: I don't have Exhibit 16.

3 May I see Exhibit 16, somebody?

4 MS. AHERN: (Tendering).

5 MR. MORIARTY: Okay. Thank you.

6 Q. (BY MR. MORIARTY) And I asked you earlier about  
7 that FDA website that first went online in July of 2009,  
8 a year and a quarter after the recall. Does that --  
9 does the FDA say anything in this website, Exhibit 38,  
10 about normal-sized tablets with too much digoxin? The  
11 Facts and Myths, it's on the second page of 38. It's  
12 probably on the second page of that one, too, the one  
13 you have there.

14 MR. MORIARTY: Do you have 38 handy?

15 MS. AHERN: Yeah (tendering).

16 Q. (BY MR. MORIARTY) Doctor, the other one is  
17 easier to read. So, I'm going to pull it out.

18 We're getting back to Exhibit 38 now.

19 MS. AHERN: Hold on.

20 MR. MORIARTY: No. I'm sorry. MDL  
21 Exhibit 38.

22 Q. (BY MR. MORIARTY) Let me find it for you, okay,  
23 Doctor?

24 A. Yes.

25 Q. Here you go, Dr. Delgado. Go on the second

1 page of that. Facts and Myths, again, the first one on  
2 the top of the second page. Let's go to the second  
3 bullet point. (Reading): Actavis detected a very small  
4 number of oversized tablets in one lot -- okay -- 20  
5 double-sized tablets in a sample of 4.8 million.

6 Although Actavis attempted to remove the affected  
7 Digitek through a visual inspection, the FDA determined  
8 that this method of removal was inadequate to assure the  
9 product's quality and consistency in accordance with  
10 good manufacturing practices.

11 Do you see that?

12 A. Yes.

13 Q. Okay. And then in the next bullet, the one we  
14 read earlier, it says (Reading): In our best judgment,  
15 given the very small number of defective tablets that  
16 may have reached the market and the lack of reported  
17 adverse events before the recall, harm to patients was  
18 unlikely.

19 So, they're talking about 20 double-thick  
20 tablets out of 4.8 million -- okay -- that Actavis  
21 removed before it shipped. Do you see that?

22 A. Yes.

23 Q. FDA is not talking about normal-sized tablets  
24 with too much digoxin, is it?

25 A. Not that I know of.



1 Q. And does it say anything here about the FDA  
2 detecting double-thick tablets that had actually been  
3 released to pharmacists or consumers?

4 MS. RUSNAK: Objection, form.

5 A. Yes. They say a small number of defective  
6 tablets may have reached the market.

7 Q. (BY MR. MORIARTY) So, a small number that was  
8 possibly making it to the market; correct?

9 A. Yes.

10 Q. Out of one batch, there were 20 with 4 -- out  
11 of 4.8 million; correct?

12 A. Yes.

13 Q. All right. You don't have any knowledge or  
14 opinion, to a probability, of how many Mimi Vega got, if  
15 any at all; correct?

16 MS. RUSNAK: Objection, form.

17 A. There's nothing discussed about any other  
18 batches. So, it's unknown.

19 Q. (BY MR. MORIARTY) And you don't know whether  
20 she got any from that batch; correct?

21 MS. RUSNAK: Objection, form.

22 Q. (BY MR. MORIARTY) From the one batch that the  
23 FDA talks about on that website?

24 A. I don't know whether she received from this  
25 batch or other batches.

Reynolds Delgado, M.D.

May 25, 2011

Page 345

1 Q. Do you know what the dose strength was of the  
2 one batch in which there were 20 double-thick tablets?

3 A. No.

4 Q. Do you know whether it was the dose strength  
5 that she was prescribed on January 13th or September  
6 14th -- September of 2007 or January of 2008 of .25?

7 A. Don't know.

8 Q. Okay. Exhibit 16 is recall information;  
9 correct?

10 A. Yes.

11 Q. And essentially it says the same thing  
12 (Reading): This product is being recalled due to the  
13 possibility that tablets with double the appropriate  
14 thickness may have been commercially released. These  
15 tablets may contain twice the approved level of active  
16 ingredient than is appropriate.

17 Correct?

18 A. Yes.

19 Q. There's nothing in Exhibit 16 that says any  
20 more than Exhibit 14 did; right?

21 A. Yes.

22 Q. Exhibit 50 is your report. Did you draft that  
23 in its entirety?

24 A. I don't remember.

25 Q. Did you do the initial draft?

Reynolds Delgado, M.D.

May 25, 2011

Page 346

1 A. I would think so, yes.

2 Q. On what computer?

3 A. I don't know.

4 Q. How many computers do you have?

5 A. Four currently, different ones I use.

6 Q. Is there a particular reason why your report is  
7 not on professional letterhead, either Delgado  
8 Cardiovascular or Texas Heart or anything else?

9 A. No particular reason.

10 Q. All right. Some doctors put it on professional  
11 letterhead, and some don't?

12 A. Uh-huh.

13 Q. There's no particular reason why yours is not?

14 A. No.

15 Q. Okay. I asked you earlier if you knew  
16 Dr. Semigran. Did you read Dr. Semigran's report or  
17 testimony in this case?

18 A. No.

19 Q. What about a Ph.D. named Nelson, Eljorn Nelson,  
20 did you read his testimony or read his report?

21 A. No.

22 Q. Was there any other documentation that was the  
23 basis for your opinion in your report about the Digitek  
24 tablets?

25 A. Not that I can remember.

1 Q. Back in -- can v-fib be a sign of overall  
2 deterioration in heart failure patients?

3 A. I don't think it specifically carries  
4 prognostic data as to the progression of heart failure.

5 Q. Okay. I'm showing you Exhibit 31. I believe  
6 this is a note originally from your fellow and that you  
7 have some handwriting on here. If you go to the second  
8 page at the very bottom, it says (Reading): VF --  
9 which, I assume, is ventricular fibrillation -- may be a  
10 sign of overall deterioration. Will plan on R and L  
11 cath tomorrow to stage need for advanced treatment.

12 Do you see that?

13 A. Yes.

14 Q. Is it in your handwriting?

15 A. Yes.

16 Q. So, what you were -- why were you trying to  
17 figure out whether this ventricular fib was a sign of  
18 overall deterioration?

19 A. Earlier you asked whether it was a sign of  
20 heart failure deterioration.

21 Q. Okay. Is it a sign of overall deterioration?

22 A. It could be, yes.

23 Q. Of her heart?

24 A. No.

25 Q. Of what?

1 A. Whole body.

2 Q. Why would whole body deterioration cause or  
3 lead to ventricular fibrillation?

4 A. Mainly electrolyte abnormalities, hormonal  
5 abnormalities, a lot of different things.

6 Q. Okay. When Dr. Seger did device evaluations of  
7 her ICD, in January of '07, he was indicating that there  
8 were more frequent daily arrhythmias. What's the  
9 significance of that?

10 A. It doesn't necessarily have any prognostic  
11 significance.

12 Q. Well, is it significant at all?

13 A. Not necessarily.

14 Q. Do you know whether you ever diagnosed  
15 Mrs. Vega with pulmonary hypertension?

16 A. I don't remember offhand.

17 Q. Exhibit 54 is a catheterization that you  
18 performed in 2002 shortly after becoming her  
19 cardiologist; correct?

20 A. Yes.

21 Q. Based just on this cath report, can you tell me  
22 whether she likely had pulmonary hypertension in 2002?

23 A. Yes.

24 Q. Did she?

25 A. She has pulmonary hypertension.

1 Q. All right. And did she continue to have  
2 pulmonary hypertension through early 2008?

3 A. Unknown.

4 Q. So, can it come and go?

5 A. Yes.

6 Q. You'd have to see more catheterizations to  
7 know?

8 A. Yes.

9 Q. And which numbers would you look at  
10 specifically to determine whether she was still in  
11 pulmonary hypertension?

12 A. Pulmonary artery pressure.

13 Q. In August of 2002, there was some reference in  
14 her chart to her being in a cardiac rehab study. Has  
15 that finally been published, that study?

16 A. I don't know what happened to that study,  
17 honestly.

18 Q. Would -- if it was published, would you have  
19 been one of the authors?

20 A. Not necessarily.

21 Q. Why would a -- did Mrs. Vega ever get a  
22 bi-valve upgrade on her ICD?

23 A. It's biventricular.

24 Q. I'm sorry. Biventricular.

25 A. I don't remember that either.

1 Q. What would be the criteria -- I know it was  
2 considered. What would be the criteria for doing that?

3 A. Mainly it has to do with the configuration of  
4 the -- of one of the waveforms on her EKG and -- that,  
5 plus, her having heart failure.

6 Q. When you say one of the "waveforms," is it  
7 something that becomes more worrisome so you want more  
8 coverage from the device?

9 A. No. Assertive configuration of the QRS  
10 waveform indicates that the patient will respond to that  
11 therapy. If you have that on the EKG, the patient is  
12 likely to improve from that therapy.

13 Q. Okay.

14 A. If you don't, they aren't.

15 Q. Do you have an opinion, to a probability, as to  
16 what Mimi Vega's serum level would have been had it been  
17 drawn January 1st, 2008?

18 A. I can't -- I can't say.

19 Q. Do you have an opinion, to a probability, what  
20 her SDC would have been had it been drawn January 14th,  
21 2008?

22 A. No.

23 Q. What about the 21st?

24 A. I can't say.

25 Q. Do you know whether her serum level of 1.2

Reynolds Delgado, M.D.

May 25, 2011

Page 351

1 drawn on January 23rd was higher than her level on any  
2 other day of the month of January, 2008?

3 A. I don't know.

4 Q. Do you have an opinion, to a probability, as to  
5 whether or not the 1.2 was higher than on any other day  
6 in January of 2008?

7 A. No.

8 Q. Could you look at Exhibit 50 again for me,  
9 please. It's your report. Go to Page 8, please.

10 A. (Witness complies).

11 Q. In Paragraph 13 you're talking about the  
12 cardiac manifestations of digoxin toxicity and then  
13 symptoms of digoxin toxicity. Where did you get all  
14 these?

15 A. I don't remember specifically.

16 Q. Well, did they come out of this "Heart Disease,  
17 a Textbook of Cardiovascular Medicine" book?

18 A. I don't remember.

19 Q. Do you remember looking at a reference and  
20 writing them all down, or did you come up with this list  
21 from your own experience without checking a reference?

22 A. Oh, I likely would have gotten this from a  
23 reference.

24 Q. But you don't know which one?

25 A. The "Heart Disease" textbook.



1 Q. Okay. Well, the last time I questioned you, I  
2 asked you what textbook you typically kept; and I think  
3 the only one you mentioned was maybe that one and  
4 "Braunwald." Could you have gotten it out of  
5 "Braunwald"?

6 A. It's possible.

7 Q. In "Braunwald," 8th Edition, Page 634, it says  
8 (Reading): The principal adverse effects of digoxin are  
9 cardiac arrhythmias, including heart block, ectopic, and  
10 reentrant cardiac rhythms.

11 Did Mimi Vega have any of those on January 22nd  
12 in that EKG, heart block or ectopic and reentrant  
13 cardiac rhythms?

14 A. I'd have to look at the EKG again.

15 Q. 41. Okay. Apparently not 41. Sorry. 38.  
16 Here's my copy, Doctor.

17 A. Thank you.

18 It's hard to assess this for digoxin toxicity  
19 because of the bundle branch block.

20 Q. Okay. Then in this book, it says (Reading):  
21 Neurological complaints such as visual disturbances,  
22 disorientation, and confusion.

23 She didn't complain of any of those on January  
24 22nd and 23rd, did she?

25 A. Not that's documented.

Reynolds Delgado, M.D.

May 25, 2011

Page 353

1 Q. All right. And you wouldn't rely on this EKG,  
2 Exhibit 38, to diagnose, to a probability, heart block  
3 or ectopic and reentrant cardiac rhythms, would you?

4 A. Correct.

5 Q. (Reading): 3, GI symptoms such as anorexia,  
6 nausea, and vomiting.

7 Did she even complain of those on January 22nd  
8 and 23rd when she was admitted?

9 A. Not that's documented.

10 Q. All right. And it doesn't even list here in  
11 Braunwald's 8th Edition that worsening heart failure is  
12 a complication of digoxin toxicity, does it?

13 A. Right.

14 Q. Okay. Exhibit 42, Doctor, is catheterization  
15 and intraaortic balloon pump February 5th, 2008;  
16 correct?

17 A. Yes.

18 Q. And the indication was cardiogenic shock and  
19 cardiomyopathy; right?

20 A. Yes.

21 Q. And do the "Findings" section mention  
22 cardiogenic shock?

23 A. Not specifically.

24 Q. All right. Severely deranged hemodynamics is  
25 something that had been on her catheterization and

Reynolds Delgado, M.D.

May 25, 2011

Page 354

1 balloon pump findings in October of 2007; correct?

2 A. Yes.

3 Q. So, it says here (Reading): Low cardiac  
4 output.

5 How many potential causes of low cardiac output  
6 are there?

7 A. Many.

8 Q. And then there's high wedge pressure; right?

9 A. Yes.

10 Q. How many potential causes of that are there?

11 A. Many.

12 Q. Did you at that time conclude, to a reasonable  
13 probability, what was causing her severely deranged  
14 hemodynamics, low cardiac output, and high wedge  
15 pressure?

16 A. I don't understand. Say that question again.

17 Q. Okay. You've got these findings here; right?

18 A. Yes.

19 Q. Did you chart a probable cause of these  
20 findings?

21 A. No.

22 Q. Do you have an opinion, to a probability, today  
23 what the cause of those findings was to a reasonable  
24 degree of medical probability?

25 A. Progressive heart failure.

1 Q. Do you have an opinion, to a probability, as to  
2 how many potential causes there are of progressive heart  
3 failure?

4 A. Again, there would be general categories, drugs  
5 being one of the big ones, concomitant illnesses, but --  
6 and then one other that's different would be progression  
7 of the underlying cardiomyopathy.

8 Q. And etiology unknown; correct?

9 A. No, I don't think that would apply.

10 Q. Do you always know the cause of progressive  
11 heart failure?

12 A. No.

13 Q. All right. I want to ask you about some of --  
14 let me ask you about 60. Do you want to put those up  
15 here if they're -- actually, the bottom ones may not  
16 be -- I think some of those came from your stack.

17 A. Yeah.

18 Q. Right. There we go.

19 This is Exhibit 60. Is this in your  
20 handwriting?

21 A. The bottom part.

22 Q. All right. I believe this is February 7th,  
23 2008, where it says "date." Is that how you write  
24 February 7th, 2008?

25 A. Yes.

1 Q. Okay. And it says above that in handwriting  
2 (Reading): Patient listed for transplant as status 1A  
3 by St. Luke's Medical Review Board.

4 Correct?

5 A. Yes.

6 Q. (Reading): Workup, possible LVAD?

7 A. Yes.

8 Q. Did you agree with the listing of her as a 1A?

9 A. I don't remember, but almost certainly I would  
10 have.

11 Q. Okay. And there are no serum digoxin  
12 concentrations ordered from the time of admission on  
13 January 31st through February 28th, 2008. Am I correct  
14 about that?

15 A. Yes.

16 Q. All right. So, is it still your opinion that  
17 the serum digoxin level of 1.2 on February 28th, 2008,  
18 is meaningful to your opinions in this case?

19 A. It depends on which opinion we're talking  
20 about.

21 Q. Okay. After a long time, it does get a little  
22 difficult to keep doing this. But in 2009 when I took  
23 your deposition, before you had written your report,  
24 what you said back then was that the two SDC levels of  
25 1.2 were a signal to you, in hindsight, that digoxin was

1 essentially the cause of her to fall off the cliff. Do  
2 you remember that?

3 A. Yes.

4 Q. And those two SDC levels of 1.2 occurred on  
5 January 23rd and February 28th. Okay?

6 A. Okay.

7 Q. I've already talked to you today about January  
8 23rd. Now, if February 28th is no longer part of your  
9 opinion in this case, for whatever reason, then I'm not  
10 going to ask you about it; but if you still believe  
11 that's a basis for your opinion that digoxin contributed  
12 to harm Ms. Vega, then I'm going to ask you about it.  
13 Does that make sense to you?

14 A. Yes.

15 Q. So, in your opinion, to a probability, is the  
16 SDC level of 1.2 drawn on February 28th, 2008, some  
17 scientific evidence to you that digoxin excess was a  
18 problem for Mrs. Vega?

19 A. Yes.

20 Q. Okay. Let me explain what I've done with  
21 Exhibit 61. Okay? I had to somehow make it thinner  
22 than it otherwise was. What this is is a collection of  
23 the medication administration records from St. Luke's  
24 Hospital for the February visit with only the digoxin  
25 pages included. Okay?

Reynolds Delgado, M.D.

May 25, 2011

Page 358

1 A. Okay.

2 Q. So, if there was a page that only had, you  
3 know, IV dextrose and whatever else she was on but did  
4 not talk about digoxin, I removed it from Exhibit 61.  
5 Okay?

6 A. Yes.

7 Q. And, further, this exhibit is broken down into  
8 three sections. Okay?

9 A. Yes.

10 Q. And the three sections represent pre-LVAD,  
11 post-LVAD intravenous, and post-LVAD oral digoxin.  
12 Okay? Got me?

13 A. Yes.

14 Q. Now, my series of questions that I'm about to  
15 ask you assumes that these medication administration  
16 records accurately reflect the brand of digoxin that  
17 Mrs. Vega was given. Okay?

18 A. Yes.

19 Q. So, if you look at the first page, which is  
20 February 2nd, it says (Reading): Digoxin tablet,  
21 Lanoxin.

22 Correct?

23 A. Yes.

24 Q. The next page, which represents February 3rd,  
25 says the same brand; correct?

Reynolds Delgado, M.D.

May 25, 2011

Page 359

1 A. Yes.

2 Q. And, of course, to the right is when the nurses  
3 gave her the medication; correct?

4 A. Yes.

5 Q. The next page, February 4th, is Lanoxin;  
6 correct?

7 A. Correct.

8 Q. The 5th, Lanoxin; correct?

9 A. Yes.

10 Q. The 6th, Lanoxin; right?

11 A. Yes.

12 Q. The 7th -- yeah. The 6th, Lanoxin; right?

13 A. Yes.

14 Q. The 7th, Lanoxin?

15 A. Okay.

16 Q. The 8th, Lanoxin; is that right?

17 A. Yes.

18 Q. The 9th, Lanoxin?

19 A. Yes.

20 Q. The 10th, Lanoxin?

21 A. Yes.

22 Q. And the 11th, it says Lanoxin, also, does it  
23 not?

24 A. Yes.

25 Q. On the 12th, it says Lanoxin; correct?



Reynolds Delgado, M.D.

May 25, 2011

Page 360

1 A. Yes.

2 Q. All right. So, that should be the first  
3 section of Exhibit 61. That's the pre-LVAD oral  
4 medications.

5 A. Yes.

6 Q. Lanoxin is not Digitek; correct?

7 A. Yes.

8 Q. And in this period of time, she was given  
9 another manufacturer's product all at the .125 dose  
10 except for the day she was admitted; correct?

11 MS. RUSNAK: Objection, form.

12 MR. MORIARTY: Okay. I'll change the  
13 form.

14 Q. (BY MR. MORIARTY) According to these MARs, if  
15 you believe what they say, she was given the .125. Was  
16 she given the .125 dose level of GSK's Lanoxin product?

17 A. Yes.

18 Q. Okay. Now, after the VAD was placed, doctor --  
19 one of the doctors wrote an order discontinuing digoxin.  
20 Are you aware of that?

21 A. No.

22 Q. I want you to assume that such an order was  
23 written probably on the 13th. Okay?

24 A. Okay.

25 Q. Now, as you flip through the second section of

1 Exhibit 61, there are no digoxin administrations which  
2 reflect that order being entered. Okay? Do you have  
3 any reason to disagree with me on that?

4 A. Okay.

5 Q. So, if you go and take these all the way  
6 through Bates No. 1386, which is quite a ways back and  
7 is this separate section that you're holding right  
8 now --

9 A. Right.

10 Q. -- there's no digoxin in there.

11 A. Okay.

12 Q. Okay. So, she was off the medication until the  
13 22nd. Do you agree with that?

14 A. Okay.

15 Q. Now, let's look at the last section of Exhibit  
16 61. Do you see that when she was restarted on digoxin,  
17 it was an intravenous dose?

18 A. Yes.

19 Q. And two pages later -- and that was on the  
20 22nd, wasn't it?

21 A. Yes.

22 Q. How many doses did she get that day based on  
23 this MAR?

24 A. One.

25 Q. So, two pages hence, is there another digoxin

1 IV prescription?

2 A. Yes.

3 Q. How many doses did she get that day?

4 A. One. It's hard to say, but at least one.

5 Q. Okay. And then if you go two pages after that  
6 on the 25th, did she get more IV digoxin?

7 A. That says "oral" --

8 Q. I'm sorry?

9 A. -- on the 25th.

10 Q. You're right. So, she got the IV doses between  
11 the 22nd and 24th; correct?

12 A. Yes.

13 Q. And by my cardiology nurse's reckoning, she got  
14 five IV doses. Do you agree or disagree?

15 A. I can't tell for sure.

16 Q. Okay. Do you have an opinion, to a reasonable  
17 degree of medical probability, what her serum digoxin  
18 level would have been if drawn late in the day on 2-24,  
19 after not having been on digoxin for a number of days  
20 and then several days' worth of IV?

21 A. I don't know.

22 Q. No opinion, to a probability?

23 A. No.

24 Q. Okay. Now let's go to the 25th.

25 Well, do you know whether Actavis makes IV

1 digoxin?

2 A. I don't.

3 Q. Well, I want you to assume they don't --

4 A. Okay.

5 Q. -- because that's a fact.

6 So, let's go to the 25th. Now the MAR says

7 Digitek; correct?

8 A. Yes.

9 Q. How many doses did she get on the 25th?

10 A. One.

11 Q. Okay. Of what dose level?

12 A. 0.125.

13 Q. All right. And I believe you told me in your  
14 first deposition that a dose of .250 would have been  
15 appropriate for her because you had prescribed it at  
16 that level from time to time; correct?

17 A. Yes.

18 Q. All right. And then on the 26th, if you go a  
19 couple days later, did she get another Digitek,  
20 according to the MAR?

21 A. Yes.

22 Q. And then did she get one on the 27th?

23 A. Yes.

24 Q. So, she got 25th, 26th and 27th, three doses of  
25 .125 Digitek; correct?

Reynolds Delgado, M.D.

May 25, 2011

Page 364

1 A. Yes.

2 Q. Do you have any opinion to a reasonable degree  
3 of medical probability whether those three tablets that  
4 she was given on those days were out of specification?

5 A. No.

6 Q. All right. So, we know that the serum digoxin  
7 level on the 28th was drawn at 5:00 in the morning --  
8 okay -- from the lab slips. What time did she get her  
9 dose on the 28th?

10 A. 0906.

11 Q. All right. So, it was after the draw; correct?

12 A. Yes.

13 Q. Now, she had a serum level of 1.2 on February  
14 28th, did she not?

15 A. Yes.

16 Q. Assuming these medication administration  
17 records accurately reflect the products given to her,  
18 what is your opinion, to a probability, as to the cause  
19 of her SDC elevation -- I'm sorry. Let me rephrase  
20 that.

21 Assuming these medication administration  
22 records are correct, do you have an opinion, to a  
23 reasonable degree of probability, as to why her serum  
24 level was 1.2 on the 28th?

25 A. It was due to the digoxin she got.

1 Q. Which product, the IV, the oral? And if you  
2 say oral, was it the Lanoxin that she got for the first  
3 12 days or the .125 Digitek that she got for the last  
4 three days?

5 MS. RUSNAK: Objection, form.

6 A. It would be the more -- the doses she received  
7 just -- in the days just prior to her blood level being  
8 drawn.

9 Q. (BY MR. MORIARTY) But you have no opinion, to a  
10 probability, as to what the dose level in those tablets  
11 was?

12 A. I don't know for a fact.

13 Q. You don't have an opinion to a probability?

14 A. No.

15 Q. You just told me that.

16 Wouldn't you agree with me that it is certainly  
17 possible that her digoxin level on February 28th of 1.2  
18 could have been caused by the administration of  
19 appropriately manufactured and dosed digoxin?

20 A. It's possible.

21 Q. Okay. And in your opinion -- do you have an  
22 opinion that it is more likely that it came from  
23 improperly-dosed digoxin -- in other words, defective  
24 tablets or IV solutions?

25 A. That is a possibility.

1 Q. During this hospitalization is it likely that  
2 she was seen by pulmonologists, cardiologists, and heart  
3 failure -- I mean heart surgeons?

4 A. Yes.

5 Q. And their fellows and residents?

6 A. Yes.

7 Q. Is it likely she was also seen by residents in  
8 internal medicine or general surgery who were rotating  
9 during -- through these disciplines?

10 A. Yes.

11 Q. Did anybody ever chart in this entire admission  
12 record that the serum level of 1.2 was concerning or  
13 reflected harm?

14 A. Not that I know of.

15 Q. Did anybody write that she had digoxin toxicity  
16 or that it was harming her?

17 A. Not that I know of.

18 Q. Did you start digoxin for atrial fibrillation  
19 on February 23rd?

20 A. I don't remember.

21 Q. The DIG trial and the Adams-Gheorghide paper,  
22 those patients only had CHF, not atrial fibrillation;  
23 correct?

24 A. Yes.

25 Q. If the literature, particularly the Gheorghide

1 and Adams paper, advocates target range of .5 to .9 for  
2 women in heart failure, how do you achieve that with  
3 your own patients if you don't routinely draw serum  
4 levels?

5 A. Dose, by dosing, just keeping the dosing  
6 proper.

7 Q. When digoxin toxicity occurs, is it usually  
8 transient, with the patient recovering with only  
9 withdrawal of the drug?

10 A. Yes.

11 Q. And then, if appropriate, and they need the  
12 inotropic activity, for heart failure patients, you can  
13 start them on the drug again; correct?

14 A. Yes.

15 Q. Typically toxicity does not cause permanent  
16 harm or death; is that right?

17 A. Yes.

18 Q. And thrombosis of peripheral vessels is not a  
19 described complication of digoxin therapy, is it?

20 A. No.

21 Q. Is that a potential risk and complication of  
22 ventricular assist devices?

23 A. Yes.

24 Q. Have you ever published any articles  
25 specifically about cardiogenic shock?



Reynolds Delgado, M.D.

May 25, 2011

Page 368

1 A. Not that I can remember.

2 Q. When you came out of your residency, were there  
3 heart failure fellowships in existence in this country?

4 A. Not really.

5 Q. Did you ever do a specific heart failure  
6 fellowship?

7 A. Yes.

8 Q. Where?

9 A. Texas Heart Institute.

10 Q. Are you still a fellow of the American College  
11 of Cardiology?

12 A. Yes.

13 Q. Do you still receive the journal of the  
14 American -- the journal of the ACC?

15 A. Yes.

16 Q. Are you a member of the AHA?

17 A. No.

18 Q. Do you follow their clinical guidelines, if  
19 they have any?

20 A. Yes.

21 Q. All right. Do they have separate guidelines  
22 than the ACC, or is it usually those ACC/AHA guidelines?

23 A. Correct. They usually collaborate.

24 Q. Do either the ACC or the AHA have ethical  
25 guidelines pertaining to testimony in medical-legal

1 matters?

2 A. I don't know.

3 Q. Have you ever checked?

4 A. No.

5 Q. Do you know whether adhering to the Code of  
6 Ethics for testifying is a condition of membership?

7 A. I don't know.

8 Q. Was there anything specific in the reports of  
9 Mann, Frishman, or Conti that leapt out at you as being  
10 scientifically inaccurate? Okay. I'm not asking  
11 whether you disagree with their conclusions. I'm asking  
12 whether there was anything about their assumptions or  
13 their method of analysis that leapt out at you as being  
14 scientifically inaccurate.

15 A. No.

16 Q. What percentage of patients who have  
17 nonischemic cardiomyopathy go on to IV milrinone or VAD  
18 or transplant, any of the three?

19 A. A small percentage. It's not the majority.

20 Q. Have you ever published a statement to the  
21 effect that LVADs have a difficult history, with  
22 patients being plagued by thrombosis, infection, and  
23 complications related to the difficult surgery required  
24 for their implantation?

25 A. Yes.

1 Q. So, a long time ago I asked you when you first  
2 expressed opinions in this case about Mrs. Vega's cause  
3 of death being related to digoxin; and I take it from  
4 your earlier testimony that the first time you ever  
5 expressed such an opinion was to one of the lawyers for  
6 Mrs. Vega's family?

7 A. I don't remember.

8 Q. Do you remember expressing such opinions to  
9 anyone other than the lawyers for her family and then me  
10 when I questioned you in 2009?

11 A. I just don't remember.

12 Q. To the best of your knowledge, has Mimi Vega's  
13 situation, from a milrinone perspective, a VAD  
14 perspective, a nonischemic cardiomyopathy perspective,  
15 or a transplant perspective, been included in any  
16 published articles?

17 A. No.

18 Q. Page 19 of Exhibit 50 says (Reading): Review  
19 of her clinical history and review of the history of the  
20 product recall and the scientific literature indicates  
21 that the levels obtained by Ms. Vega were in the range  
22 of the fatalities caused by this improperly-manufactured  
23 product.

24 It's at the end of your Paragraph 28. Do you  
25 see it?

1 A. Yes.

2 Q. What are you talking about, the fatalities  
3 caused by this improperly-manufactured product?

4 A. Probably it's better-worded "fatalities which  
5 may be caused."

6 Q. Okay. I mean, you're not aware of any  
7 prerecall instances where a defective tablet was known  
8 to have caused a fatality, are you?

9 A. No.

10 Q. I just have a couple more, and then I'll turn  
11 this over to Hunter.

12 Let's -- let's try to put yourself in October  
13 of 2007 -- okay --

14 A. Okay.

15 Q. -- and everything you knew about Mimi Vega at  
16 that point based on her echocardiograms, her caths, her  
17 clinical course, et cetera. Okay?

18 A. Yes.

19 Q. For a woman with her findings, test results,  
20 and clinical condition, what were her chances of  
21 survival on oral medical management alone for one year?

22 A. I don't think that can be determined.

23 Q. Would it be less than 50 percent?

24 A. I don't think I can say.

25 Q. Okay. Well, when you made the decision to put

1 her on IV milrinone at home, were there statistics and  
2 experience at play in your mind that were telling you  
3 that unless I bridged her to transplant with this  
4 milrinone therapy, her chances of survival on this oral  
5 therapy alone were not good?

6 A. I don't think that was necessarily my thinking.  
7 In fact, she had been stable for a prolonged period of  
8 time; and, perhaps, my thinking may have been that I  
9 could use the milrinone as a quick means of  
10 restabilizing her -- in other words, she'd be able to be  
11 weanable.

12 Q. When was somebody going to try to wean her?  
13 Wean her? Better pronounce those right.

14 A. Yes.

15 Q. Transcript will be funny.

16 A. I don't know specifically.

17 Q. Okay. But if you have a patient on IV  
18 milrinone who meets the criteria for IV milrinone, the  
19 chances of survival for one to two years is 30 percent  
20 or less; correct?

21 A. It depends on the study you believe.

22 Q. Well, I think the studies in your papers have  
23 30 percent or less; correct?

24 A. My own paper showed a -- I believe it was 23  
25 percent mortality at a year.

Reynolds Delgado, M.D.

May 25, 2011

Page 373

1 Q. Okay. What was it at two years?

2 A. I don't believe we studied that.

3 Q. All right. What's the survival of patients  
4 overall on LVADs as bridge to transplant for one to two  
5 years?

6 A. Currently, it's one year, approximately 85  
7 percent. That's current technology.

8 Q. Is there literature out there co-authored by  
9 Dr. Frazier that indicates that LVAD patients have 52  
10 percent survival at one year, 29 percent at two years?

11 A. There likely is, yes.

12 Q. Okay. Is there also likely literature out  
13 there co-authored by Dr. Frazier that medical management  
14 alone has survival of 28 percent at one year and 13  
15 percent at two?

16 A. Yes.

17 Q. Okay. I may have asked you something about  
18 this before; but this REMATCH trial, were you an  
19 investigator for REMATCH?

20 A. No.

21 Q. All right. Here's Exhibit 57. Was anybody at  
22 Texas Heart or St. Luke's an investigator on the REMATCH  
23 trial?

24 A. Yes, Frazier and Mason.

25 Q. Okay. And this article, Exhibit 57, which you

1 co-authored in 2007, it talks about REMATCH results and  
2 things about heart failure and its prognosis; correct?

3 A. Yes.

4 Q. And presumably this would have been -- you  
5 know, you were writing this and making the final  
6 publication in the year when decisions were being made  
7 about Mimi Vega's milrinone and workup for a VAD and  
8 transplant; correct?

9 A. Yes.

10 Q. All right. Doctor, I think I'm done.

11 A. Okay.

12 Q. You want to take a five-minute break before  
13 Hunter organizes her stuff and questions you?

14 A. Sure.

15 MS. RUSNAK: I need a bathroom break, if  
16 we can.

17 (RECESS FROM 7:33 P.M. TO 7:39 P.M.)

18 MR. MORIARTY: We have -- I'm doing an  
19 exhibit reconciliation during the break. So, we have  
20 10-A. And then starting with 20 -- because we had 19  
21 exhibits at his first session in 2009. So, we have 20,  
22 21, 22, 26, 27, 28, 29, 30, 31, 32, 34, 35, 36, 37, 38,  
23 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 49-A, 51,  
24 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62 and 63. Now,  
25 the vast majority of these, I premarked for the

1 convenience of everybody in the room so we did not have  
2 to slow down with marking exhibits. And there are  
3 several missing from this stack. There's at least one  
4 that I know I did not actually mark and bring and use  
5 because -- well, just because.

6 The record should also note there are  
7 going to be two Exhibit 38s. One is from the Vega case  
8 specifically for this deposition. The other 38 is an  
9 MDL defense exhibit which is the FDA's website on "Facts  
10 and Myths For Generic Drugs." So, I will try to dig  
11 around and see what we're missing.

12 MS. RUSNAK: Do you know what you're  
13 missing, or you don't know?

14 MR. MORIARTY: I read them all off. I  
15 know one of them is 50, which is Dr. Delgado's report.  
16 So, I'm going to dig through my stack over here. And  
17 then any that Teri winds up not having --

18 MS. RUSNAK: We'll be happy to copy for  
19 you.

20 MR. MORIARTY: -- I'll be happy to copy or  
21 supply them to her. Okay? But I'm going to look  
22 through my own stack down here and see.

23 EXAMINATION

24 BY MS. AHERN:

25 Q. Dr. Delgado, I know it's been a very, very long



1 day; but you realize this is our only opportunity to ask  
2 you about your report and your opinions and support for  
3 your opinions?

4 A. Okay.

5 Q. I just want to go back and make sure that I  
6 understand as much as I can some of the things we  
7 discussed earlier; and, so, I'll ask some follow-up  
8 questions. And one of the things I wanted to ask you  
9 about is earlier on, Mr. Moriarty talked to you about  
10 probability versus possibility and discussed the term  
11 "reasonable degree of medical probability." Do you  
12 remember that discussion?

13 A. Yes.

14 Q. Okay. In your report you've expressed opinions  
15 to a reasonable degree of medical probability?

16 A. Yes.

17 Q. I just want to make sure that we understand  
18 your definition of reasonable degree of medical  
19 probability because we kind of went back and forth on  
20 that, and I just want to know what you define that as in  
21 your report.

22 A. Medical probability is how I said it earlier,  
23 just how we determine that in medical -- in the medical  
24 field is perhaps different than the legal field. But  
25 it's how I termed it earlier.

1 Q. Okay. And I'm sorry. I don't exactly  
2 remember, or maybe I didn't understand how you termed it  
3 or how you explained it. And I'm only interested in  
4 your definition for the sake of your report. So, if  
5 there is a legal definition that attaches and you have a  
6 different one, I just want to know what yours is.

7 A. I just don't remember exactly what I said in  
8 the beginning of the deposition, but it would be that.

9 Q. Would it be -- I'm trying to recall that.  
10 Would it be greater than 50 percent probability?

11 A. It's whatever I initially said at the beginning  
12 of the deposition.

13 Q. Okay. Well --

14 A. I just don't recall the exact words.

15 Q. So, whatever you said earlier, you're sticking  
16 with?

17 A. Is the answer, yes.

18 Q. Okay. And I want to talk a little bit about  
19 your methodology. In your report you say the  
20 methodology that you used to arrive at your opinions in  
21 this case was a differential diagnosis?

22 A. If that's what you're reading, yes.

23 Q. Okay. So that you reviewed the patient's  
24 clinical history and chart, available medical records,  
25 recall records and data, along with any pertinent

1 medical or scientific literature, and the patient's  
2 clinical presentation; and you formulated an opinion as  
3 to the most probable cause of Mimi Rivera-Vega's death;  
4 is that correct?

5 A. If you're reading directly from my statement,  
6 then yes.

7 Q. Do you normally review recall records and data  
8 as part of the differential diagnosis for a patient?

9 A. No.

10 Q. How often in the past have you reviewed recall  
11 records or FDA data as part of your differential  
12 diagnosis?

13 A. I'd say it's rare but not unheard of.

14 Q. But it's certainly not routine?

15 A. Correct.

16 Q. Okay. And could you walk us through your  
17 differential diagnosis in this particular case?

18 A. Of what specifically?

19 Q. Cause of death.

20 A. Her death was caused by heart failure.

21 Q. Dr. Delgado, differential diagnosis is a  
22 process by which a physician like yourself will generate  
23 a list of likely causes for a patient's symptoms and  
24 then systematically rule out those causes until they end  
25 up with the most likely cause. Is that an accurate

1 description of a differential diagnosis?

2 A. (Moving head side to side).

3 Q. Okay. Would you --

4 A. No.

5 Q. -- explain what a differential diagnosis is,  
6 what the process is?

7 A. It's a list of the possible causes of  
8 something.

9 Q. Okay. In this case it would be a list of  
10 possible causes for Ms. Rivera-Vega's death?

11 A. Yes.

12 Q. And in addition to heart failure, what other  
13 causes did you consider?

14 A. Well, it depends on what do you mean by causes  
15 of death and -- I think it depends on what you mean by  
16 "cause."

17 Q. And what do you mean by "cause"?

18 A. Well, when I say "heart failure," that's --  
19 that's the overall cause; and it may not be the mode of  
20 death, how she actually died. It may not be the  
21 proximate cause. It may not be the underlying illness,  
22 but it's the overall cause.

23 Q. Okay. And what is proximate cause?

24 A. The thing that mostly is related to the death  
25 in time, temporally related.

1 Q. So, what other modes -- that's not a correct  
2 term, I guess. Did you say "mode," might not be the  
3 "mode" by which she died, heart failure? What was the  
4 term that you used? I'm sorry.

5 A. That the mode of death may be thought of as the  
6 terminal event, meaning ventricular fibrillation arrest  
7 or respiratory failure, what actually happened seconds  
8 before she was declared dead.

9 Q. Okay. And can you tell me where digoxin fits  
10 in in terms of your thinking here, cause of death for  
11 Mimi Rivera-Vega?

12 A. The digoxin caused the worsening of heart  
13 failure that led to the progression of need for advanced  
14 therapies and subsequent death.

15 Q. Okay. And I want to ask you a little bit about  
16 that, about digoxin and worsening heart failure. What  
17 is the physiological mechanism by which digoxin can  
18 cause worsening heart failure, in your opinion?

19 A. The true answer to that is not known.

20 Q. Are there any publications that you can direct  
21 us to that support your opinion that digoxin can cause  
22 worsening heart failure?

23 A. The -- the best studies in that are related  
24 to -- or are written about other inotropes rather than  
25 digoxin. Milrinone is -- there's a lot written about

1 milrinone.

2 Q. But you're not aware of any studies that  
3 support digoxin specifically causing worsening heart  
4 failure?

5 MS. RUSNAK: Objection, form.

6 A. There are studies that have elucidated the  
7 mechanism -- the actual mechanism of action, how that  
8 happens.

9 Q. (BY MS. AHERN) Okay. Are there studies that  
10 generally support that proposition?

11 A. Likely.

12 Q. Are you aware of any specific studies?

13 A. No.

14 Q. And we talked a little bit about the DIG trial  
15 earlier, and one of the DIG trial's findings was that  
16 digoxin actually prevented or decreased the number of  
17 hospitalizations due to worsening heart failure; is that  
18 correct?

19 A. Yes.

20 Q. How do you reconcile your opinion that digoxin  
21 causes worsening heart failure with the DIG trial's  
22 results?

23 A. It's -- it's the amount -- it's in the amount.  
24 Like most cardiovascular drugs, it's a bell-shaped curve  
25 as to the effect of the drug and too little is worse and

1 too much is worse and balancing to stay at the top of  
2 the bell-shaped curve is the key.

3 Q. And the bell-shaped curve would be -- in this  
4 case, what would the bell-shaped curve represent?

5 A. It's a curve that looks like a bell.

6 Q. True. But what would it represent?

7 MS. RUSNAK: Objection, form.

8 A. It would represent the patient's exposure to a  
9 particular drug and the clinical benefit versus  
10 detriment.

11 Q. (BY MS. AHERN) And I'm going to skip real quick  
12 to amiodarone. Doctor, we already talked a little bit  
13 about amiodarone's effects on digoxin levels and that it  
14 can increase the digoxin levels?

15 A. Yes.

16 Q. Are you aware of any publication that supports  
17 your statement earlier that amiodarone's effects on  
18 serum digoxin concentrations is dependent on the dose of  
19 amiodarone?

20 A. Not aware of any publications.

21 Q. Is that based on your -- is your statement  
22 based on your experience with amiodarone?

23 A. Yes.

24 Q. And how do you normally monitor patients that  
25 you prescribe amiodarone to who are also taking digoxin?

Reynolds Delgado, M.D.

May 25, 2011

Page 383

1 A. You don't.

2 Q. So, you don't routinely take serum digoxin  
3 concentrations in patients who are on amiodarone?

4 A. No.

5 Q. So, how do you determine whether or not there  
6 is a potentially dangerous increase in digoxin levels on  
7 a patient taking amiodarone?

8 A. If you give a high dose of amiodarone, then  
9 you, at the same time, cut the dose of the digoxin.

10 Q. And what is a high dose of amiodarone, in your  
11 opinion?

12 A. 800 a day -- milligrams.

13 Q. How often do you prescribe an 800-milligram  
14 dose of amiodarone to patients?

15 A. At least once a week.

16 Q. Would you consider that to be a relatively  
17 standard dose?

18 A. Depends on what you're treating.

19 Q. Okay. If you're treating -- well, what would  
20 you prescribe amiodarone and digoxin for?

21 A. Usually atrial fibrillation.

22 Q. Would you use amiodarone with digoxin in any  
23 other context?

24 A. Occasionally.

25 Q. What sorts of things?



1 A. Possibly treating other arrhythmias, other  
2 types of arrhythmias.

3 Q. Okay. What types of arrhythmias?

4 A. Well, amiodarone can treat a variety of  
5 supraventricular and ventricular tachycardias.

6 Q. Patients who were taking -- who you prescribed  
7 amiodarone to for those types of arrhythmias, would they  
8 also be taking digoxin?

9 A. Not necessarily.

10 Q. Can you think of a context in which they would  
11 be taking both, if you were treating for a ventricular  
12 arrhythmia?

13 A. Yes.

14 Q. In what sort of context?

15 A. Someone who has two different problems,  
16 ventricular arrhythmia and heart failure or ventricular  
17 arrhythmia and a-fib, for example.

18 Q. Has it ever been your practice when prescribing  
19 amiodarone to cut the dig dose in half?

20 A. Uh-huh. Sorry. Yes.

21 Q. Is there a particular reason that you didn't do  
22 so in the case of Ms. Vega?

23 A. From what I can see, I only used a low dose of  
24 amiodarone on her.

25 Q. Do you recall what that dose was?

Reynolds Delgado, M.D.

May 25, 2011

Page 385

1 A. 100 milligrams.

2 Q. Do you know what the half-life of amiodarone  
3 is?

4 A. It depends.

5 Q. And what does it depend on?

6 A. On the volume of distribution you're talking  
7 about. It's a very complicated drug in its  
8 pharmacokinetics.

9 Q. Can it take several weeks for the effects of  
10 amiodarone to reach their potential maximum?

11 A. Depends on the effects.

12 Q. Antiarrhythmic effects.

13 A. Depends on the arrhythmia.

14 Q. When is the last time you reviewed the  
15 Cordarone or the Pacerone labels?

16 A. Not recently.

17 Q. And to what extent do you rely on your pharmacy  
18 at the hospital to point out any drug interactions to  
19 you when you prescribe?

20 A. I think they're very good at it.

21 Q. Do you normally research that yourself with the  
22 labels of various drug products in the PDR, or do you  
23 generally rely on the staff -- pharmacy staff?

24 A. It depends on if it's a drug that I have  
25 experience with or not. And certainly the computer

1 programs help us, too.

2 Q. And what kind of computer programs do you use  
3 at St. Luke's?

4 A. eClinical is the one I use in my office.  
5 St. Luke's has other programs. I don't know the actual  
6 names. EMRs.

7 Q. All right. Really quickly, jumping back to  
8 methodology, the differential diagnosis, other than, you  
9 know, excessive digoxin, what other potential causes for  
10 Mimi Rivera's death did you rule in when you were  
11 considering factors that could have caused her death?  
12 That's a bad question. I apologize. Strike that.

13 When you were doing your differential diagnosis  
14 in this case, other than excessive digoxin, what other  
15 factors or things did you rule in as potential causes  
16 for Mimi Rivera's death?

17 A. I don't think you can express it in that way.  
18 It's a chain of events that led to her death.

19 Q. So, you didn't --

20 A. The underlying cause was heart failure.

21 Q. Okay. But you didn't generate a list of  
22 potential causes and then go through each one and knock  
23 them out and end up with digoxin?

24 A. No. Like I said, it's a chain of events.

25 Q. Okay. And do you normally perform a

1 differential diagnosis retrospectively to determine  
2 cause of death?

3 A. No, no.

4 Q. It's kind of an odd use for a differential  
5 diagnosis?

6 A. Well, it depends on what you're using it for.  
7 Occasionally we will create a differential diagnosis on  
8 an ME document, medical examiner document, for a medical  
9 examiner.

10 Q. But usually you use it to diagnose a living  
11 patient's particular condition --

12 A. Yes.

13 Q. -- so you can treat it?

14 A. Yes.

15 Q. Okay. I think that that's all I have.

16 MS. AHERN: I'll check my notes one more  
17 time, if that's okay with you.

18 MS. RUSNAK: (Moving head up and down).

19 MR. MORIARTY: She's probably triggered  
20 five questions for me.

21 MS. RUSNAK: I knew that was going to  
22 happen.

23 MR. MORIARTY: At least the number's  
24 getting smaller.

25 MS. RUSNAK: You promise?

1 MR. MORIARTY: You want me to wait for  
2 you?

3 MS. AHERN: No. You can go ahead.

4 REEXAMINATION

5 BY MR. MORIARTY:

6 Q. In answer to one of Hunter's questions, you  
7 said something about in your opinion, digoxin caused the  
8 worsening of heart failure which led to the progression  
9 of need for advanced therapies. Okay?

10 A. Yes.

11 Q. That's what I want to ask you about. What  
12 advanced therapies are you talking about?

13 A. LVAD transplant.

14 Q. You are not including milrinone in the advanced  
15 therapies category?

16 A. No.

17 Q. All right. And to make sure that I understand  
18 the sequence correctly, in October of 2007 and then into  
19 November of 2007, the workup for a VAD and transplant  
20 had already started; correct?

21 A. I don't remember specifically.

22 Q. We went through those notes where -- "likely  
23 need VAD," et cetera, in October and November; right?

24 A. That doesn't mean it was started, though. We  
25 often get curtailed by -- even if our intent is to start

1 at that time, we're often curtailed by third-party  
2 payers, other reasons.

3 Q. But medically, in your mind, her condition  
4 warranted the workup for a VAD and a transplant starting  
5 in October of 2007?

6 (REPORTER CLARIFICATION)

7 Q. (BY MR. MORIARTY) In your mind, medically --  
8 forget third-party payers or anything else. Medically,  
9 in October of 2007 and in November, you had said "likely  
10 need VAD and workup for VAD and transplant"; correct?

11 A. I said those things on my --

12 Q. Okay.

13 A. -- on my notes at that time.

14 Q. And once she was started on the IV milrinone,  
15 you knew that the long-term survival with that was well  
16 less than 50 percent and, more likely than not, she  
17 would need to be converted to a VAD at some point;  
18 correct?

19 A. Well, depends on what you call long-term. Just  
20 as an example, I have one patient in the hospital right  
21 now who's been on IV milrinone three different times  
22 over ten years and a total of probably four years on  
23 milrinone; and he's still alive. So --

24 Q. Well, statistics are what they are; and we've  
25 talked enough about those.

1           So, I think what Hunter was trying to get at  
2     and I'm not clear on is you believe that worsening heart  
3     failure caused her death. Your original domino in the  
4     chain, in your opinion, is digoxin. So, as part of the  
5     differential diagnosis, what other potential causes of  
6     worsening heart failure did you consider in the  
7     differential and then rule out?

8           A. Well, I can't comment now on what my thinking  
9     was then; but in general, I would say a concomitant  
10    illness, for example; progression of the underlying  
11    cardiomyopathy, for example. An example of postpartum  
12    cardiomyopathy progressing, the underlying  
13    cardiomyopathy, would be if a woman gets pregnant again.  
14    That obviously wasn't the case with her, but that's just  
15    an example. Another underlying concomitant illness  
16    would be, say, urinary tract infection or pneumonia, you  
17    know, something else or a totally separate insult to the  
18    heart like, for example, myocardial infarction just  
19    happened to happen just due to coronary disease.

20          Q. Okay. And then I think you said drugs were in  
21    the potential list?

22          A. Right.

23          Q. And --

24          A. A good example is Adriamycin.

25          Q. Okay. And she's on a lot of other medications

1       besides digoxin; correct?

2           A.     Yes.

3           Q.     Anything else that could have been in the  
4       possible list?

5           A.     Not that I can think of offhand.

6           Q.     Okay. And is it your opinion, to a  
7       probability -- I don't want to go through each one of  
8       these in detail. Is it your opinion, to a probability,  
9       that you've ruled out all but digoxin as the initial  
10      precipitating cause of her decline?

11          A.     Yes.

12          Q.     Okay. And when did this decline actually  
13      start?

14          A.     It's not entirely clear.

15          Q.     Well, she was admitted on January 22nd very  
16      late in the day, discharged on the 25th. So, she's  
17      under medical care and can be watched and tested. And  
18      she's readmitted on the 31st. Okay? In -- and if you  
19      want to go back into earlier January, that's fine. Do  
20      you have an opinion, to a reasonable degree of  
21      probability, when this worsening heart failure began or  
22      when she, in your terms, fell off the cliff?

23          A.     Yeah. That's very difficult to pinpoint  
24      because it doesn't necessarily apply or have anything to  
25      do with the volume overload episode.



1           Q.    So, are you telling me you don't have an  
2    opinion as to when this worsening of the heart failure  
3    began in January or February, 2008?

4           A.    Roughly in that time frame, I can say; but  
5    specific -- I can't be specific.

6           Q.    Okay. That's all I have.

7                       MS. RUSNAK: Okay. We will reserve for  
8    trial.

9                       (DEPOSITION CONCLUDED AT 8:10 P.M.)

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1 THE STATE OF TEXAS:

2 COUNTY OF JEFFERSON:

3 I, TERI DAIGLE, a Certified Shorthand Reporter,  
4 hereby certify that the foregoing testimony was given  
5 before me after the Witness had been first duly sworn.

6 I further certify that this transcript was typed  
7 under my direction and that it is a complete and correct  
8 copy of the transcript of the proceedings; and that it  
9 is being returned to the attorney taking same to be  
10 filed by if necessary.

11 I further certify that I am neither attorney for,  
12 related to, nor employed by any of the parties to the  
13 lawsuit in which this deposition was taken. Further, I  
14 am neither related to nor employed by any attorney of  
15 record in this cause; nor do I have a financial interest  
16 in the matter.

17 GIVEN UNDER MY HAND AND SEAL OF OFFICE in Beaumont,  
18 Texas, on this the \_\_\_\_\_ day of \_\_\_\_\_,  
19 2011.

20 \_\_\_\_\_  
21 TERI DAIGLE, RPR, TCRR  
22 Texas CSR No. 4441/Louisiana CCR No. 23043  
23 Expiration Date: December 31, 2011  
24 Nell McCallum & Associates, Inc.  
25 Firm Registration No. 143  
2615 Calder Avenue, Suite 111  
Beaumont, Texas 77702

Reynolds Delgado, M.D.

May 25, 2011

DEPOSITION REVIEW  
CERTIFICATION OF WITNESS

ASSIGNMENT NO.35349

CASE NAME:Digitek Products Liability Litigation

DATE OF DEPOSITION:May 25, 2011

WITNESS' NAME: Reynolds Delgado, M.D.

In accordance with the Rules of Civil Procedure,  
I have read the entire transcript of my testimony or it  
has been read to me.

I have made no changes to the testimony as  
transcribed by the court reporter.

\_\_\_\_\_  
Date Witness

Sworn to and subscribed before me, a Notary Public in  
and for the State and County, the referenced witness did  
personally appear and acknowledge that:

They have read the transcript;  
They signed the foregoing sworn Statement; and  
Their execution of this Statement is of their free  
act and deed.

I have affixed my name and official seal this \_\_\_\_\_  
day of \_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_  
Notary Public

\_\_\_\_\_  
Commission Expiration Date

Reynolds Delgado, M.D.

May 25, 2011

1 DEPOSITION REVIEW

CERTIFICATION OF WITNESS

2 ASSIGNMENT NO. 35349

3 CASE NAME: Digitek Products Liability Litigation

4 DATE OF DEPOSITION: May 25, 2011

5 WITNESS' NAME: Reynolds Delgado, M.D.

6 In accordance with the Rules of Civil Procedure,  
7 I have read the entire transcript of my testimony or it  
8 has been read to me.

9 I have listed my changes on the attached Errata  
10 Sheet, listing page and line numbers as well as the reason(s)  
11 for the change(s).

12 I request that these changes be entered as part of the  
13 record of my testimony.

14 I have executed the Errata Sheet, as well as this  
15 Certificate, and request and authorize that both be appended  
16 to the transcript of my testimony and be incorporated therein.

17 \_\_\_\_\_  
18 Date Witness

19 Sworn to and subscribed before me, a Notary Public in  
20 and for the State and County, the referenced witness did  
21 personally appear and acknowledge that:

22 They have read the transcript;  
23 They have listed all of their corrections in the  
24 appended Errata Sheet  
25 They signed the foregoing sworn Statement; and  
Their execution of this Statement is of their free  
act and deed.

26 I have affixed my name and official seal this \_\_\_\_\_  
27 day of \_\_\_\_\_, 20\_\_\_\_.

28 \_\_\_\_\_  
29 Notary Public

30 \_\_\_\_\_  
31 Commission Expiration Date

Reynolds Delgado, M.D.

May 25, 2011

## 1 ERRATA SHEET

2 RENNILLO DEPOSITION &amp; DISCOVERY - A VERITEXT COMPANY

3 ASSIGNMENT NO. 35349

4 CASE NAME: Digitek Products Liability Litigation v.

5 DATE OF DEPOSITION: May 25, 2011

6 WITNESS' NAME: Reynolds Delgado, M.D.

PAGE/LINE(S)/	CHANGE	REASON
6	____/____/____	____/____
7	____/____/____	____/____
8	____/____/____	____/____
9	____/____/____	____/____
10	____/____/____	____/____
11	____/____/____	____/____
12	____/____/____	____/____
13	____/____/____	____/____
14	____/____/____	____/____
15	____/____/____	____/____
16	____/____/____	____/____
17	____/____/____	____/____
18	____/____/____	____/____

19 \_\_\_\_\_  
20 Reynolds Delgado, M.D.

21 SUBSCRIBED AND SWORN TO BEFORE ME THIS \_\_\_\_\_

22 DAY OF \_\_\_\_\_, 20\_\_\_\_.

23 \_\_\_\_\_  
24 NOTARY PUBLIC

25 MY COMMISSION EXPIRES \_\_\_\_\_